IRRIGATION SETS (MALTA ACCESS CODES): DESIGN INPUTS – REQUIREMENTS

Approvals

Signatures below indicate approval that all content has been transferred from already approved documentation to this one.

FUNCTION	NAME	SIGNATURE	DATE
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1 PURPOSE

The purpose of this document is to define the Design Input - Requirements of Malta design owned Access Codes.

2 SCOPE

The scope of this document is to provide an overview of the Design Input requirements applicable to the product codes in the following DHF families:

- Irrigation Sets

3 UPDATES OF SCOPE

Updates in scope of this revision were done to complete Correction Action PR#527666 by Parent Record: #517380 (on TW9). Nature of updates is to update the list of applicable standards (adding and removing as applicable to the codes in scope) in the design input documents (of both DHFs 81542 and 85000) and to confirm if referenced standards are state of the art. If not to provide a gap assessment.[1]

4 REFERENCE DOCUMENTS

Reference Number	Title
BXU535425	Irrigation Sets (Malta Access Codes) User Needs and Intended Use
1239908	Access System Design Failure Mode and Effects Analysis (DFMEA)
1277545	Viaflex Irrigation Hazard and Interoperability Assessment (HAZOP)
GQP-12-08	Evaluation of TSE and Virus Risks for Materials used in Baxter Processes

5 LIST OF PRODUCT COMPLIANCE STANDARDS

The scope of this section is to list all the standards and respective revisions that the current effective access codes requirements are fully or partially compliant to.

Standard Reference	Title	Status
European Pharmacopeia: Monograph 3.3.7	EP (11th Edition Monograph 3.3.7) : Sets for transfusion of blood and blood components	**Current**
ISO 10993-1:2018 (BS EN ISO 10993-1:2020)	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management	**Current**
BS EN ISO 8536-4 + A1: 2013	Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed	**Superseded by:** BS EN ISO 8536-4: 2020 (2020-03-17) **Revision Assessment:** BXU578694
BS EN ISO 8536-4: 2020	Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed	**Current**
BS EN ISO 556-1: 2001	Sterilization of medical devices. Requirements for medical devices to be designated “Sterile” - Part 1: Requirements for terminally sterilized medical devices.	**Superseded by:** BS EN 556-1:2024 (2024-07-03) **Revision Assessment:** BXU614511
BS EN 556-1:2024	Sterilization of medical devices. Requirements for medical devices to be designated “Sterile” - Part 1: Requirements for terminally sterilized medical devices.	**Current**
ISO 11228-1: 2003	Ergonomics - Manual handling Part 1: Lifting and carrying	**Superseded by:** ISO 11228-1:2021 (2021-10-05) **Revision Assessment:** No impact. Only 1 requirement (MAC-SYR.304) is referring to this standard, referring to Annex A.7.2. In new revision, annex location has been transferred to C.1.3.1 with no changes to the 0.75m requirement specification. Requirement reference needs to be updated accordingly.
ISO 11228-1:2021	Ergonomics - Manual handling Part 1: Lifting and carrying	**Current**
BS EN ISO 11607-1: 2009+A1:2014	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems.	**Superseded by:** BS EN ISO 11607-1:2017 (2018-05-15) BS EN ISO 11607-1:2020 (2020-01-20) BS EN ISO 11607: 2020 + A11:2022 (2023-11-06) BS EN ISO 11607-1:2020+A1:2023 (2023-11-06) **Revision Assessment:** BXU600943SR
BS EN ISO 11607-1:2020+A1:2023	Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems.	**Current**
BS EN 868-5:2009	Packaging for terminally sterilized medical devices	**Superseded by:** BS EN 868-5:2018 (2019-01-07) **Revision Assessment:** Refer to rationale in BXU552207/B Attachment 2
BS EN 868-5:2018	Packaging for terminally sterilized medical devices	**Current**

Notes:

1. The scope of this document captures all the requirements of legacy Irrigation codes, as well as new product developments. Design input requirements updates captured within a revision of this DHF document, would be limited to the specific subset of codes and / or requirements in scope of the specific change control or new product development. Hence for legacy codes and their respective design input requirements to be updated/aligned to the latest standards might not be updated straight away when a new revision is issued. Due to the different timelines and priorities between different product changes/updates its very likely and acceptable to have multiple revisions of a standard referenced across

[1] As required by Audit Observation record: #542631 (on TW9)

different codes or within the same code, provided that a revision assessment of that standard is clearly documented and referenced in this section. The revision assessment of a standard update needs to list the updates between the two revisions and the impact, if any, to the legacy codes (including product design, input requirements, verification, validation, etc)

2. The list of standards in this section, needs to be reviewed with every revision of the document, regardless of the scope of the update, at minimum adding or updating any new standard references and the respective status of the revision assessment. Required updates of any legacy codes, and respective requirements, will be determined once the revision assessment is completed. If a new revision of this design input requirements document is required prior to the completion of a revision assessment, a justification provided by the PDO and Quality is required to assess the risk to proceed with the new revision of this requirements document.

6 DEFINITIONS

For definitions, see GLOSSARY (Baxter's Glossary).

Term	Definitions
SYR	System Requirements
LAR	Labelling Requirements
REG	Regulatory Requirements (Requirements from applicable Norms)
MIT	Risk Mitigations (requirements from applicable Risk Files: 1239908 & 1277545)
UNIU	User Needs and Intended Uses (requirements from User Needs and Intended Uses: BXU535425)
VER	Design Verification

7 REQUIREMENT CATEGORIES

Category	Definitions
Functionality	The Functionality requirements state "what" the system must do.
Performance	The Performance requirements state "how well" a function is to be performed.
Regulatory	The Regulatory requirements define requirements applicable to a product to meet specific product, regional, or global standards or laws.
Interface	The Interface requirements state how components, subsystems and systems interact with each other.
Conditioning	The Conditioning requirements state the conditions after which the product shall remain functional.
Labelling	The Labelling requirements include labelling requirements as specified by Regulatory, product compliance standards, and/or labelling risk mitigations as identified in the Risk Management File.

8 REQUIREMENTS (DESIGN INPUTS)

8.1 Product Family: Irrigation Sets

Code: 7400009A

Description: Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes:	Yes	Conditioning	Critical Dimension(s)	BOM Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	- integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.			Material(s) Product Shelf Life	Engineering Drawing		**MIT.7** - Set shall maintain functionality during Shelf Life.	or surgical sterile field.	
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)		Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-	The set shall include a spike which is compatible	Yes	Functional	Set	BOM	N/A	**MIT.19** - The set shall include the minimum	**MAC-UNIU.33** - I need to be able to	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
SYR.611	Clearflex Clearflex container closures.			Configuration			and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	administer solution from a collapsible container.	
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-	The silicon tube shall be attached and detached	Yes	Functional	Critical	BOM	N/A	**MIT.5** - Set shall maintain functionality	**MAC-UNIU.149** - I need to be able to	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
SYR.638	from the catheter adaptor to a maximum of 3 times.			Dimension(s) Material(s)	Blueprint Engineering Drawing		after sterilization.	attach and detach the catheter adaptor to and from the silicone tube for multiple times.	
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A

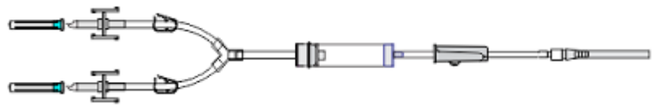
SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: 7401010A

Description: Y Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:



SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than	Yes	Functional	Length of Set	BOM Blueprint Engineering	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	1500mm in length.				Drawing				
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	- non-toxic over the shelf life period.								
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)								
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
									clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.						barrier.		
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: E5MC4002

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference	Yes	Regulatory	Material(s)	BOM Material Card(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5	**MIT.1** - The fluid path contact materials shall be chemically and biologically	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	and medical device classification in accordance with ISO 10993-1.				Part Specification(s)	BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	or surgical sterile field.	
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	- non-toxic over the shelf life period.								
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							and correct components required to control the flow rate. (flow regulator & drop former)		contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

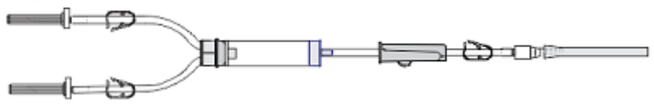
SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.						standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.		
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: E5MC4007N

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:



SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than	Yes	Functional	Length of Set	BOM Blueprint Engineering	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	1500mm in length.				Drawing				
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical	Yes	Conditioning	Critical	BOM	N/A	**MIT.5** - Set shall maintain functionality	**MAC-UNIU.12** - I need to administer	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	quality attributes: - integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.			Dimension(s) Material(s) Product Shelf Life	Blueprint Engineering Drawing		after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	irrigation solution to the irrigation site and or surgical sterile field.	
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)								
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.		contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a:	Yes	Performance	Critical Dimension(s)	Blueprint Engineering	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)			Material(s)	Drawing			container.	
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							the intended period of use.		
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10			
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: EMC4002A

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference	Yes	Regulatory	Material(s)	BOM Material Card(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5	**MIT.1** - The fluid path contact materials shall be chemically and biologically	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	and medical device classification in accordance with ISO 10993-1.				Part Specification(s)	BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	or surgical sterile field.	
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.60	Sterile product shall remain integral and sterile	Yes	Conditioning	Critical	BOM	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality	**MAC-UNIU.12** - I need to administer	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination		Regulatory	Dimension(s) Material(s) Packaging Configuration Set Configuration	Blueprint Engineering Drawing		after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
									ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	2. Maximum removal force of 90N at a removal rate of 100 mm/min								
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							MIT.37 - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	continuous bladder irrigation for up to 72 hours using the same set.	
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-	Each primary packaging shall contain an individual	Yes	Functional	Set	BOM	BS EN ISO 8536-4, Clause 10	**MIT.43** - Packaging shall act as a sterile	**MAC-UNIU.19** - I need a set that can be	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
SYR.301	set.		Regulatory	Configuration		BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	barrier. **MIT.49** - Set is individually packed.	used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: EMC4015N

Description: Fast Flow Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A
MAC-	The set shall conform to the biological	Yes	Regulatory	Material(s)	BOM	ISO 8536-4:2019, Clauses 9.1,	**MIT.1** - The fluid path contact materials	**MAC-UNIU.12** - I need to administer	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
SYR.743	requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.				Material Card(s) Part Specification(s)	9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	irrigation solution to the irrigation site and or surgical sterile field.	
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	- sterile - non-toxic over the shelf life period.			Life					
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)								
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							the intended period of use.		relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	rate of 100 mm/min (for ClearFlex Twin Valve)								
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.621	The irrigation chamber shall include an irrigation bubble trapper (conical filter)	Yes	Functional	Set Configuration	BOM	N/A	**MIT.29** - The set shall include the minimum and correct components required to eliminate air particles entrained within the fluid path.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.624	Irrigation chambers containing an air trapper device (bubble filter) shall not allow more than 1ml of air after flushing 1.2L of irrigation solution at a flow rate of 600ml/min.	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-	The clamp shall not cause functional damage to the	Yes	Performance	Critical	BOM	N/A	**MIT.5** - Set shall maintain functionality	**MAC-UNIU.30** - I need to be able to control	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
SYR.649	tube during the shut off period of 12 hours.			Dimension(s) Material(s)	Blueprint Engineering Drawing		after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

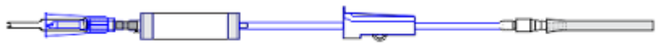
SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	(23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.						**MIT.39** - Labels shall reflect applicable Baxter requirements.		
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.307	Paper band adhesive shall not be transferred onto set.	No	Functional	Material(s)	Blueprint	ISO 11607-1:2009+A1:2014	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.308	Paper band shall be easily removable. Note: Minimum Requirement: As guidance, the removal force shall not be greater than 20N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.63** - No excessive force required to remove paper band/sleeve.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: EMC4042

Description: Single Lead Irrigation Set (Easy Flow Uni-Set)

DHF Family: Irrigation Sets

Diagram:



SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product	Yes	Conditioning	Critical Dimension(s) Material(s)	BOM Blueprint Engineering	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	- dose accuracy - sterile - non-toxic over the shelf life period.			Product Shelf Life	Drawing		during Shelf Life.		
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note:	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.					BS EN ISO 1135-5, Clause 6.7			ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.612	The set shall include a spike which is compatible with Easyflow container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.613	When the Easyflow spike is used with an Easyflow container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 145N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.614	When the Easyflow spike is used with an Easyflow container, it shall have a minimum removal force of 15N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s)	BOM Blueprint	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
				Material(s)	Engineering Drawing		**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	needed.	
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm.	Yes	Performance	Critical Dimension(s)	BOM Engineering	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.			Material(s)	Drawing		**MIT.61** - No excessive force required to open primary packaging.		
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014			
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: EMC4047

Description: Y-Type Irrigation Set (Easy Flow Multi-Set)

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than 1500mm in length.	Yes	Functional	Length of Set	BOM Blueprint Engineering Drawing	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile - non-toxic	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	over the shelf life period.								
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
									provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.612	The set shall include a spike which is compatible with Easyflow container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.613	When the Easyflow spike is used with an Easyflow container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 145N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.614	When the Easyflow spike is used with an Easyflow container, it shall have a minimum removal force of 15N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							the intended period of use.		
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note:	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.								
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							Baxter requirements.		
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.307	Paper band adhesive shall not be transferred onto set.	No	Functional	Material(s)	Blueprint	ISO 11607-1:2009+A1:2014	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.308	Paper band shall be easily removable. Note: Minimum Requirement: As guidance, the removal force shall not be greater than 20N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.63** - No excessive force required to remove paper band/sleeve.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: EMC4055N

Description: Y-Type Irrigation Set (Easy Flow Ultra-Set)

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including	Yes	Functional	Length of Set	BOM Blueprint	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	intermediate components, shall be not less than 1500mm in length.				Engineering Drawing		container to the patient.		
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.123	The drip chamber shall permit continuous observation of the fall of drops.	Yes	Functional Regulatory	Material(s)	Blueprint	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.24** - The set shall have a sufficiently translucent fluid path. **MIT.33** - The set shall include the minimum and correct components required to	**MAC-UNIU.29** - I need to be able to see drops falling in the drip chamber.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
							control the flow rate. (flow regulator & drop former)		irrigation chamber drop visibility. The chamber drop visibility provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.129	The drip chamber shall permit squeezing to facilitate the priming procedure. Note: Minimum Requirements: As a guideline, the force required to squeeze the drip chamber walls shall not exceed: - Moulded drip chamber: 91N - RF Welded chamber: 22N Preferred Requirement: With changes, the opening force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.8 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.10 BS EN ISO 1135-4, Clause 5.7 BS EN ISO 1135-5, Clause 6.7	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chambers and priming. The provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.192	The set shall include an on/off roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.193	The set shall include a regulating roller clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former) **MIT.36** - Flow regulator shall maintain the set flow rate within an acceptable limit. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.26** - I need a set that is capable of retaining the desired flow rate. **MAC-UNIU.27** - I need to be able to regulate to the desire flow rate. **MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.539	The roller clamp shall withstand activation and de-activation without causing: - Functional damage to the tube - Roller to pop out of frame track.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
					Drawing	BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.219	The roller clamp shall allow activation and de-activation. Note: Minimum Requirements: As guidance activation and de-activation force shall not exceed: - 93N for small roller clamps - 46N for medium roller clamps - 144N for large roller clamps. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.33** - The set shall include the minimum and correct components required to control the flow rate. (flow regulator & drop former)	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.612	The set shall include a spike which is compatible with Easyflow container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.613	When the Easyflow spike is used with an Easyflow container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 145N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.614	When the Easyflow spike is used with an Easyflow container, it shall have a minimum removal force of 15N at a removal rate of 100 mm/min	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.620	The set shall include an irrigation chamber	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.621	The irrigation chamber shall include an irrigation bubble trapper (conical filter)	Yes	Functional	Set Configuration	BOM	N/A	**MIT.29** - The set shall include the minimum and correct components required to eliminate air particles entrained within the fluid path.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.624	Irrigation chambers containing an air trapper device (bubble filter) shall not allow more than 1ml of air after flushing 1.2L of irrigation solution at a flow rate of 600ml/min.	Yes	Functional	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.627	The roller clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014			
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.307	Paper band adhesive shall not be transferred onto set.	No	Functional	Material(s)	Blueprint	ISO 11607-1:2009+A1:2014	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.308	Paper band shall be easily removable. Note: Minimum Requirement: As guidance, the removal force shall not be greater than 20N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.63** - No excessive force required to remove paper band/sleeve.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: RMC4916

Description: Irrigation Set

DHF Family: Irrigation Sets

Diagram:

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility			
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical quality attributes: - integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.	Yes	Conditioning	Critical Dimension(s) Material(s) Product Shelf Life	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.		N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 1135-5, Clause 6.5			
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo) Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal rate of 100 mm/min	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause	Yes	Performance Regulatory	Critical Dimension(s)	BOM Engineering	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.			Material(s)	Drawing		**MIT.43** - Packaging shall act as a sterile barrier.		
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.61** - No excessive force required to open primary packaging.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A

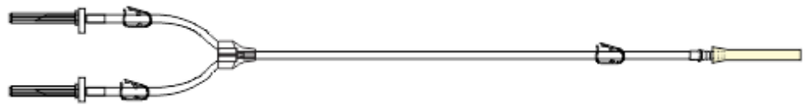
SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 1135-5, Clause 10			
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

Code: VMC4005

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:



SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
MAC-SYR.5	The set shall conform to the chemical requirements described as per ISO 8536-4:2013+A1:2013, Clause 7.	Yes	Functional Regulatory	Fluid Contact Surface Area Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 7 BS EN ISO 8536-5, Clause 7 BS EN ISO 8536-8, Clause 7 BS EN ISO 8536-12, Clause 7 BS EN ISO 8536-13, Clause 7	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.35** - Materials used are compatible with sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding chemical testing. The chemical provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.7	When the set is tested in accordance with ISO 8536-4:2013+A1:2013, Annex A.1, the number of particles detected shall not exceed the contamination index limit.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.1 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.1 BS EN ISO 8536-12, Clause 6.1 BS EN ISO 8536-13, Clause 6.2	**MIT.4** - Set shall meet applicable standards controlling the particulate matter generation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	Note: This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.9	Any connections between the components of the set, excluding protective caps, shall withstand a static tensile force of not less than 15N applied along the longitudinal axis for 15s.	Yes	Performance Regulatory	Critical Dimension(s) Insertion depth Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.3 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.2 BS EN ISO 8536-9, Clause 5.3 BS EN ISO 8536-10, Clause 4.3 BS EN ISO 8536-11, Clause 5.3 BS EN ISO 8536-12, Clause 6.2 BS EN ISO 8536-13, Clause 6.3	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding tensile strength. The tensile strength provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.605	The set shall allow a flow rate of at least 200 ml water in 1 min under a static head of 0.6m.	Yes	Functional Regulatory	Fluid Path Cross Sectional Dimensions Length of Set	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.3	**MIT.9** - The set shall allow the intended gravimetric flow rate.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.606	The irrigation set shall show no signs of leakage when tested in accordance with ISO 16391:2002 Clause 6.2.	Yes	Functional Regulatory	Critical Dimension(s) Material(s) Solvent(s)	BOM Blueprint Engineering Drawing	BS EN ISO 16391:2002 Clause 4.2	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.607	The length of the set from the silicone tube (distal end) to the irrigation chamber, including intermediate components, shall be not less than	Yes	Functional	Length of Set	BOM Blueprint Engineering	N/A	**MIT.26** - The set's length shall be sufficiently long to allow connection of IV container to the patient.	**MAC-UNIU.31** - I need a set with sufficient length for use.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	1500mm in length.				Drawing				
MAC-SYR.743	The set shall conform to the biological requirements described as per standard reference and medical device classification in accordance with ISO 10993-1.	Yes	Regulatory	Material(s)	BOM Material Card(s) Part Specification(s)	ISO 8536-4:2019, Clauses 9.1, 9.3, 9.4 and 9.5 BS EN ISO 8536-4:2013+A1:2013, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 8536-5:2013, Clause 8 BS EN ISO 8536-8:2015, Clause 8 BS EN ISO 8536-9:2015, Clauses 7.2 and 7.2 BS EN ISO 8536-10:2015, Clauses 6.2 and 6.3 BS EN ISO 8536-11:2015, Clauses 7.2 and 7.3 BS EN ISO 8536-12:2007+A1:2013, Clauses 8.2 and 8.3 BS EN ISO 8536-13:2016, Clause 8 BS EN ISO 1135-4:2015, Clauses 7.1, 7.3, 7.4 and 7.5 BS EN ISO 1135-5:2015, Clauses 8.1, 8.3, 8.4 and 8.5 BS EN ISO 16391:2002 Clause 4.6 ISO10993-1:2018 FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)]:2008, Section 11, Biocompatibility	**MIT.1** - The fluid path contact materials shall be chemically and biologically compatible. **MIT.2** - The non fluid path contact materials shall be biocompatible. **MIT.5** - Set shall maintain functionality after sterilization. **MIT.35** - Materials used are compatible with sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.639	The irrigation set shall show no signs of leakage when the collapsible container is subjected to a pressure cuff exerting a pressure 300mmHg.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.24** - I need to be able to use a pressure cuff on the collapsible container to transfer fluids at a higher flow rate.	N/A
MAC-SYR.51	The product shall be designed using materials which conform to GQP-12-08.	No	Regulatory	Material(s)	BOM Blueprint	GQP-12-08		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.52	The product shall not be manufactured with natural rubber latex.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.42** - The set shall consist of components that do not contain natural rubber latex.	**MAC-UNIU.60** - I need a latex free product.	N/A
MAC-SYR.53	Product that contains PVC (polyvinyl Chloride) shall meet the 0.1 % m/m limit of DEHP (di-2ethyl hexyl phthalate) as per Baxter regulatory requirement.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.41** - The set shall meet the acceptable limit of DEHP.	**MAC-UNIU.57** - I need a Non DEHP set.	N/A
MAC-SYR.54	The product shall be designated 'sterile' via a sterilization process conforming to BS EN 556-1:2001, Clause 4.	Yes	Conditioning Regulatory	Sterilization Process	BOM	BS EN 556-1	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.55	The product shall be sterilized via EO sterilization.	No	Conditioning	Sterilization Process	BOM	N/A			N/A
MAC-SYR.57	The product shall have a vented system to allow the ingress/egress of EO sterilization gas in order to have a sterilized fluid path.	Yes	Conditioning	Sterilization Process Venting Components: Location, Number, Dimensions, Materials	BOM Blueprint	N/A	**MIT.44** - EO sterilized sets shall allow ingress/egress of EO sterilization.		N/A
MAC-SYR.59	The product shall maintain the desired critical	Yes	Conditioning	Critical	BOM	N/A	**MIT.5** - Set shall maintain functionality	**MAC-UNIU.12** - I need to administer	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	quality attributes: - integrity of product - dose accuracy - sterile - non-toxic over the shelf life period.			Dimension(s) Material(s) Product Shelf Life	Blueprint Engineering Drawing		after sterilization. **MIT.7** - Set shall maintain functionality during Shelf Life.	irrigation solution to the irrigation site and or surgical sterile field.	
MAC-SYR.60	Sterile product shall remain integral and sterile throughout distribution: - No damaged to primary packaging (sterility barrier system) - No open paper band* - No defects leading to loss of component integrity *Note: when opening sterile pouch over a sterile cloth, clinician requires set to remain coiled in order to prevent contamination	Yes	Conditioning Regulatory	Critical Dimension(s) Material(s) Packaging Configuration Set Configuration	BOM Blueprint Engineering Drawing	BS EN ISO 11607-1, Clause 6.1.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.6** - Set shall maintain functionality after transportation.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.70	The tubing of the set shall be transparent or sufficiently translucent as to allow visual detection of air bubbles inside the fluid path.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 6.6 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.11 BS EN ISO 8536-9, Clause 5.1 BS EN ISO 1135-4, Clause 5.5 BS EN ISO 1135-5, Clause 6.5	**MIT.24** - The set shall have a sufficiently translucent fluid path.	**MAC-UNIU.32** - I need to be able to prime the set and remove any residual air from the fluid path.	N/A
MAC-SYR.76	The protective cap shall be easily removable from the interfacing spike by an axial motion. Note: Minimum Requirement: As a guidance, the removal force shall not exceed 22N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.13 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.13 BS EN ISO 8536-9, Clause 5.10 BS EN ISO 8536-10, Clause 4.6 BS EN ISO 8536-11, Clause 5.6 BS EN ISO 8536-12, Clause 6.9 BS EN ISO 1135-4, Clause 5.12 BS EN ISO 1135-5, Clause 6.12	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding removal of protective caps. The protective caps removal provisions of ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 3.6.
MAC-SYR.81	The set shall include a non-vented spike at the proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.83	The set shall include two leads with a non-vented spike at each proximal end.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.16** - The set shall include the minimum and correct components required to deliver solution/blood to patient. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.37** - I need to be able to connect multiple containers, to administer sequential therapies.	N/A
MAC-SYR.534	The spike shall withstand re-insertions into respective unused containers.	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.105	When the spike is used with a flexible container closure it shall have a: 1. Maximum insertion force of 145 N at an insertion rate of 100 mm/min (if tested with a Viaflo) 2. Maximum removal force of 90 N at a removal rate of 100 mm/min (if tested with a Viaflo)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	Irrigation Sets are not used with Viaflo bags. Therefore requirement for Viaflex bags applies.

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Or 1. Maximum insertion force of 233 N at an insertion rate of 100 mm/min (if tested with a Viaflex) 2. Maximum removal force of 145 N at a removal rate of 100 mm/min (if tested with a Viaflex)								
MAC-SYR.194	The set shall include a notched clamp.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.559	The notch clamp shall withstand 18 activation and de-activation cycles without causing functional damage to the tube.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.560	The notch clamp shall be capable of performing shut off following 18 activation and de-activation cycles.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	BS EN ISO 8536-4, Clause 6.9 BS EN ISO 8536-5, Clause 6.1 BS EN ISO 8536-8, Clause 6.12 BS EN ISO 1135-4, Clause 5.8 BS EN ISO 1135-5, Clause 6.8	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.40** - The shut off clamp shall not damage the interfacing tube. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	This is not a regulatory requirement for Irrigation Sets. The standard for irrigation sets ISO16391:2002 does not contain provisions regarding roller clamps and/or notch clamps. The relevant roller clamps/notch clamps provisionsof ISO 8536-4:2013+A1:2013 are being adapted. Refer to BXU535238 Section 4.2.
MAC-SYR.221	The notched clamp shall allow activation and de-activation. Note: Minimum Requirements: As a guidance activation and de-activation force shall not exceed: - 50N for single step Notched Clamp - 120N for multiple step Notched Clamp. Preferred Requirement: With changes, the activation and de-activation force of the new design shall be comparable to the current one.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.610	The set shall include a spike which is compatible with Viaflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.611	The set shall include a spike which is compatible Clearflex Clearflex container closures.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.615	When the irrigation set spike is used with an Clearflex container closure it shall have a: 1. Maximum insertion force of 200N at an insertion rate of 500 mm/min 2. Maximum removal force of 90N at a removal	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	rate of 100 mm/min								
MAC-SYR.616	When the irrigation set spike is used with a Clearflex container closure it shall have a: a. Minimum removal force of 15N at a removal rate of 100 mm/min (for Clearflex Standard Valve) b. Minimum removal force of 15N at a removal rate of 100 mm/min (for ClearFlex Twin Valve)	Yes	Performance	Critical Dimension(s) Material(s)	Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.33** - I need to be able to administer solution from a collapsible container.	N/A
MAC-SYR.625	The clamp shall be capable of shutting off flow at a head height of 0.6m.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	ISO 16391, Clause 6.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.626	The clamp shall maintain shut off for the period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.37** - The set shall include the minimum and correct components required to shut off the flow.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed.	N/A
MAC-SYR.633	The Catheter Adaptor shall be attached to the silicon tube with a maximum insertion force of 75N at an insertion rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.634	The Catheter Adaptor shall be detached from the silicon tube with a maximum removal force of 120N at a removal rate of 100mm/min	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.635	The Catheter Adaptor shall be detached from the silicon tube with a minimum removal force of 15N at a removal rate of 100mm/mm	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.19** - The set shall include the minimum and correct components required to deliver irrigation solution to urinary drainage catheter and/or surgical scope.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field. **MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.638	The silicon tube shall be attached and detached from the catheter adaptor to a maximum of 3 times.	Yes	Functional	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.149** - I need to be able to attach and detach the catheter adaptor to and from the silicone tube for multiple times.	N/A
MAC-SYR.649	The clamp shall not cause functional damage to the tube during the shut off period of 12 hours.	Yes	Performance	Critical Dimension(s) Material(s)	BOM Blueprint Engineering Drawing	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.34** - The flow regulator shall not damage the interfacing tube. **MIT.37** - The set shall include the minimum and correct components required to shut off the flow. **MIT.46** - Set shall maintain functionality for the intended period of use.	**MAC-UNIU.30** - I need to be able to control the flow, turning on and off flow as needed. **MAC-UNIU.148** - I need to perform continuous bladder irrigation for up to 72 hours using the same set.	N/A
MAC-SYR.294	Seal strength shall be greater or equal to 1.2N per 15mm when tested as per ISO 868-5:2009, Clause 4.5.1. Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 868-5, Clause 4.5.1	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.295	The pouch shall facilitate ease of opening, with maximum seal strength of 10.5N/15mm.	Yes	Performance	Critical Dimension(s)	BOM Engineering	N/A	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
	Note: Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs. For Sterile Packaging; this requirement verifies the aseptic opening for respective pouch.			Material(s)	Drawing		**MIT.61** - No excessive force required to open primary packaging.		
MAC-SYR.296	The seal between bottom web and top web shall be continuous and homogeneous. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Critical Dimension(s) Material(s)	BOM Engineering Drawing	BS EN ISO 11607-1, Clause 5.1.9	**MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.297	During peeling of top web from bottom web, no delamination or tearing of the material that can affect opening and presentation shall occur. Note: 1. Test method as per ISO 868-5, Annex E - Method for the determination of peel characteristics of paper/plastic laminate products, is applicable. 2. Unless further specified condition samples at (23 ± 2) °C and (50 ± 5) % relative humidity for a minimum of 24hrs.	Yes	Performance Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.1.9	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.298	Primary packaging materials shall act as a sterile barrier.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.2	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.43** - Packaging shall act as a sterile barrier.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A
MAC-SYR.299	Bottom web shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	BOM Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.300	Printed label shall be legible (i.e. no smears, smudging and/or fading of label). Note: Unless further specified condition samples at (23± 2)°C and (50± 5)% relative humidity for a minimum of 24hrs.	Yes	Labelling Regulatory	Ink Material(s)	BOM Blueprint	BS EN ISO 11607-1, Clause 5.4	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.301	Each primary packaging shall contain an individual set.	Yes	Functional Regulatory	Set Configuration	BOM	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8 BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10	**MIT.43** - Packaging shall act as a sterile barrier. **MIT.49** - Set is individually packed.	**MAC-UNIU.19** - I need a set that can be used in a sterile field. **MAC-UNIU.56** - I need individually packed sets.	N/A
MAC-SYR.302	Each primary package shall be sealed in a tamper-evident manner.	Yes	Functional Regulatory	Material(s)	BOM Blueprint	BS EN ISO 8536-4, Clause 10 BS EN ISO 8536-5, Clause 10 BS EN ISO 8536-8, Clause 9 BS EN ISO 8536-9, Clause 8 BS EN ISO 8536-10, Clause 7 BS EN ISO 8536-11, Clause 8	**MIT.50** - Packaging of the set is sealed in a tamper evident manner.	**MAC-UNIU.19** - I need a set that can be used in a sterile field.	N/A

SYR ID	SYR REQ.	CORE REQ.	REQUIREMENT TYPE	CQA	EDO	REG REQ.	MIT REQ.	UNIU REQ.	NOTES
						BS EN ISO 8536-12, Clause 9 BS EN ISO 1135-4, Clause 9 BS EN ISO 1135-5, Clause 10 BS EN 16679:2014			
MAC-SYR.303	Product shall be supplied in a carton.	Yes	Functional	Set Configuration	BOM	N/A	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.304	The carton shall have a maximum width of 0.75m so as to allow handling as per ISO 11228-1:2003, Annex A.7.2.	Yes	Functional Regulatory	Critical Dimension(s)	Blueprint	BS EN ISO 11228-1, Annex A.7.2	**MIT.52** - Sets are shipped in a carton of standard size and shape to facilitate transport and stacking.		N/A
MAC-SYR.305	Labelling printed directly on the carton and/or carton label shall be legible (i.e. no smears, smudging and/or fading of label).	Yes	Labelling	Ink Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A
MAC-SYR.306	The product shall include a paper band to retain the set in a coiled position.	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.307	Paper band adhesive shall not be transferred onto set.	No	Functional	Material(s)	Blueprint	ISO 11607-1:2009+A1:2014	**MIT.5** - Set shall maintain functionality after sterilization.	**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.308	Paper band shall be easily removable. Note: Minimum Requirement: As guidance, the removal force shall not be greater than 20N. Preferred Requirement: With changes, the removal force of the new design shall be comparable to the current one.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.5** - Set shall maintain functionality after sterilization. **MIT.63** - No excessive force required to remove paper band/sleeve.	**MAC-UNIU.55** - I need to be able to open the packaging with my hands.	N/A
MAC-SYR.309	The product shall include a plastic bag/sleeve to retain the set in a coiled position	No	Functional	Set Configuration	BOM	N/A		**MAC-UNIU.12** - I need to administer irrigation solution to the irrigation site and or surgical sterile field.	N/A
MAC-SYR.310	Plastic bag/sleeve material shall be transparent or sufficiently translucent as to allow visualisation of the set.	Yes	Functional	Material(s)	Blueprint	N/A	**MIT.57** - Clear bottom web on primary packaging for product visibility.	**MAC-UNIU.54** - I need to be able to see the set through the packaging.	N/A
MAC-SYR.313	The adhesive label shall remain attached to its substrate (i.e. carton or pouch).	Yes	Labelling	Material(s)	BOM	N/A	**MIT.38** - Labels shall reflect applicable standards. **MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.	N/A

9 REVISION HISTORY

REVISION	ISSUE DATE	REASON FOR CHANGE
A	Refer to Stamp	New Document as per Change Control-2018-005514 (PR 1547148).
B	Refer to Stamp	As per Change Control-2017-006240(PR#1367849).
C	Refer to Stamp	i) Aligned Biological Requirement MAC-SYR.608 into MAC-SYR.743 as a Requirements Standardization effort. ii) Updated System Requirements as per PR#1464965 (Change Control-2018-002710). Updates performed as per BXU560137, Attachment 2. iii) Updated System Requirements as per PR#1402097 (Change Control-2018-000464). Updates performed as per BXU566288 - Attachment 2, BXU570230 – Attachment 1 and BXU571857 – Attachment 4. iv) Updated System Requirements as per PR#376171 (Change Control-2014-006542). Updates performed as per BXU561782 – Attachment 5.
D	Refer to Stamp	Updates competed to complete Correction Action PR#527666 by Parent Record: #517380 (on TW9). Nature of updates is to update the list of applicable standards in the design input documents (of both DHFs 81548 and 85000), to confirm if referenced standards are state of the art and if not to provide a gap assessment.

Baxter

TcU ELECTRONIC SIGNATURE REPORT

REVISION INFORMATION

Item ID: BXU535427	**Revision ID:** D
Item Name: IRRIGATION SETS (MALTA ACCESS CODES): DESIGN INPUTS - REQUIREMENTS	**Release Date:** 30-Jan-2025
Description:	

CHANGE INFORMATION

CN/CR Number (if applicable):

Description of Change (This field will be blank if required data is not available):

Updates in scope of this revision were done to complete Correction Action PR#527666 by Parent Record: #517380 (on TW9). Nature of updates is to update the list of applicable standards (adding and removing as applicable to the codes in scope) in the design input documents (of both DHFs 81542 and 85000) and to confirm if referenced standards are state of the art. If not to provide a gap assessment.

Reason for Change (This field will be blank if required data is not available):

Updates in scope of this revision were done to complete Correction Action PR#527666 by Parent Record: #517380 (on TW9). Nature of updates is to update the list of applicable standards (adding and removing as applicable to the codes in scope) in the design input documents (of both DHFs 81542 and 85000) and to confirm if referenced standards are state of the art. If not to provide a gap assessment.

APPROVALS & SIGNATURES for Document Release

Name	Role	Workflow Step	Date of Signature	Decision Taken
Omes, Bryan	Author	Initiate Review	30-Jan-2025	Approved
Debono, David	SME	Document Review - SME & Quality	30-Jan-2025	Approved
Bartolo, Maria	Quality	Document Review - SME & Quality	30-Jan-2025	Approved
Omes, Bryan	Author	Document Review - SME & Quality	30-Jan-2025	Approved
Psaila, Cynthia	Change Specialist 3	Release Document(s)	30-Jan-2025	Approved
Psaila, Cynthia	Change Specialist 3	Set Effectivity	30-Jan-2025	Approved