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

Approvals

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

FUNCTION	NAME	SIGNATURE	DATE
R&D (Author)	Bryan Omes	(See Electronic Signature)	(See stamp)
R&D (PDO)	David Debono	(See Electronic Signature)	(See stamp)
Quality	Maria Bartolo	(See Electronic Signature)	(See stamp)

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1 PURPOSE

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

2 SCOPE

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

- Irrigation Sets

3 UPDATES IN 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)

5 DEFINITIONS

Term	Definitions
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)

6 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 labelling requirements are fully or partially compliant to.

Standard Reference	Title	Status
BS EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	**Superseded by:** BS EN ISO 15223-1: 2021 (2021-09-29) **Revision Assessment:** BXU570944SR
BS EN ISO 15223-1: 2021	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	**Current**

Notes:

1. The scope of this document captures all the labelling requirements of legacy Irrigation codes, as well as new product developments. Labelling 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 labelling 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 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 from a design perspective.
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 labelling requirements, will be determined once the revision assessment is completed. If a new revision of this labelling 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.

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

7 LABELLING REQUIREMENTS (DESIGN INPUTS)

7.1 Product Family: Irrigation Sets

Code: 7400009A

Description: Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.40	Labelling shall indicate that the set is DEHP plasticized, using the graphical symbol as given in BS EN 15986:2011. Note: Information may be included in insert p.n. 20002430 or symbol definition leaflet.	Yes	Carton Primary Packaging	ISO 15986:2011 MDD (93/42/EEC) Annex I, section 7.5 as amended by 2007/47/EC (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.41	Labelling shall include indication to refer to the Instructions for Use leaflet. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Primary Packaging	ISO 15223-1:2016 (For Brazil) RDC 185 / 2001, Annex III.B 2.8, 3.1 (2001) Colombia: Decree no 4725/2005, Article 53 (2005) (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008. 4.1.1.9 (2008) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.58** - Product is required to have legible label.	
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.207	Labeling text shall be available in Slovakian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.56	Labelling text shall be available in Polish language.	No	Carton Primary Packaging	Art. 14, Act No. 107/679 on Medical Devices; 20.May.2010	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.57	Labelling text shall be available in Russian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.58	Labelling text shall be available in Czech language.	No	Carton Primary Packaging	Act No. 268/2014 Coll., on medical devices; 22.Oct.2014 Questions on the Use of Medical Devices, September 13, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.64	Labelling shall include barcode. Note: This requirement is applicable to the primary packaging.	Yes	Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.78	Labelling shall provide instructions to fill the chamber to a certain level. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	N/A	**MIT.73** - Where applicable, labelling shall provide instructions to fill the chamber to a certain level.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.115	Labelling shall include warnings not to use product if sterility protectors are loose or missing. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.128	Labelling shall include the ARTWORK document number	Yes	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.6 (q) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.218	Labelling text shall be available in Croatian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.219	Labelling text shall be available in Slovenian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.220	Labelling text shall be available in Estonian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.221	Labelling text shall be available in Latvian language.	No	Carton Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

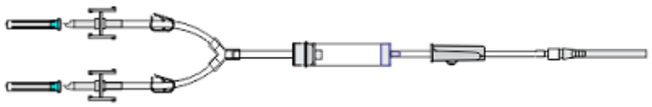
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.222	Labelling text shall be available in Lithuanian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.223	Labelling text shall be available in Hungarian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.225	The Unit Label / Unit Packaging label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.226	The Inner Carton label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.227	The Unit Label / Unit Packaging label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.228	The Carton label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.230	The Unit Label / Unit Packaging label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.231	The carton label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.232	In Unit label / unit packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.233	In carton packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.234	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the AIDC format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.235	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the AIDC format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.236	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the HRI format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.237	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the HRI format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

Code: 7401010A

Description: Y Set for Urological Irrigation

DHF Family: Irrigation Sets

Diagram:



LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.			ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.40	Labelling shall indicate that the set is DEHP plasticized, using the graphical symbol as given in BS EN 15986:2011. Note: Information may be included in insert p.n. 20002430 or symbol definition leaflet.	Yes	Carton Primary Packaging	ISO 15986:2011 MDD (93/42/EEC) Annex I, section 7.5 as amended by 2007/47/EC (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.41	Labelling shall include indication to refer to the Instructions for Use leaflet. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Primary Packaging	ISO 15223-1:2016 (For Brazil) RDC 185 / 2001, Annex III.B 2.8, 3.1 (2001) Colombia: Decree no 4725/2005, Article 53 (2005) (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008. 4.1.1.9 (2008) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.207	Labeling text shall be available in Slovakian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.56	Labelling text shall be available in Polish language.	No	Carton Primary Packaging	Art. 14, Act No. 107/679 on Medical Devices; 20.May.2010	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.57	Labelling text shall be available in Russian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.58	Labelling text shall be available in Czech language.	No	Carton Primary Packaging	Act No. 268/2014 Coll., on medical devices; 22.Oct.2014 Questions on the Use of Medical Devices, September 13, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.64	Labelling shall include barcode. Note: This requirement is applicable to the primary packaging.	Yes	Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.78	Labelling shall provide instructions to fill the chamber to a certain level. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	N/A	**MIT.73** - Where applicable, labelling shall provide instructions to fill the chamber to a certain level.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.115	Labelling shall include warnings not to use product if sterility protectors are loose or missing. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.116	Labelling shall include a pictorial illustration of the product. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	No	Primary Packaging	N/A	**MIT.55** - Labelling shall include product description.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.128	Labelling shall include the ARTWORK document number	Yes	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.6 (q) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.218	Labelling text shall be available in Croatian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.219	Labelling text shall be available in Slovenian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.220	Labelling text shall be available in Estonian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.221	Labelling text shall be available in Latvian language.	No	Carton Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.222	Labelling text shall be available in Lithuanian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.223	Labelling text shall be available in Hungarian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.225	The Unit Label / Unit Packaging label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.226	The Inner Carton label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.227	The Unit Label / Unit Packaging label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.228	The Carton label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.230	The Unit Label / Unit Packaging label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.231	The carton label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.232	In Unit label / unit packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.233	In carton packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.234	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the AIDC format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.235	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the AIDC format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.236	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the HRI format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.237	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the HRI format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

Code: E5MC4002

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.16	Labelling shall include recommended storage conditions, if any.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(i) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.3 (4); 13.4 (3)(7) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.53** - Where applicable, labelling shall indicate storage and handling conditions.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.					**MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.207	Labeling text shall be available in Slovakian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.59	If labelling uses any trademark(s) the following text (or similar) shall be included: "Trademark" is a trademark of "Trademark Owning Company". Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU	Yes	Carton Primary Packaging	Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter Trademark and Copyright Policy Effective: 1.Jan.2016 (document available as Baxter 04 in GLAM document library) Baxter Corporate Trademark Database: http://corporate.inbaxter.com/law/trademarks/index.html?WT.svl=globalheader&cat=Tools&app=Trademark	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.128	Labelling shall include the ARTWORK document number	Yes	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.6 (q) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.190	Labeling shall contain the name and address of the importer for Colombia.	No	Carton Primary Packaging	(For Colombia) Decree no 4725/2005, Article 54 e; 55 b; 57	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.192	Labeling shall contain the registration number or marketing permit for Colombia.	No	Carton Primary Packaging	(For Colombia) Decree no 4725/2005, Article 54 d; 57	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.184	Labeling shall contain the registration number preceded by "RS No" or the phrase "Registro sanitario No." for Peru Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	(For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138 For instructions for use:	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Supreme decree 016-2011-SA (27.Jul.2011) Article. 140		
MAC-LAR.219	Labelling text shall be available in Slovenian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.220	Labelling text shall be available in Estonian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.225	The Unit Label / Unit Packaging label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.226	The Inner Carton label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.227	The Unit Label / Unit Packaging label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.228	The Carton label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.230	The Unit Label / Unit Packaging label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.231	The carton label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.232	In Unit label / unit packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.233	In carton packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.234	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the AIDC format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.235	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the AIDC format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.236	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the HRI format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.237	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the HRI format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.240	Labelling shall Indicate that the irrigation set is non-iv Compatible. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.241	Labelling shall indicate the irrigation set can be used under a maximum allowable pressure of 300mmHg. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.243	Labelling shall contain the name and address of the importer or distributor for Peru.	No	Primary Packaging	(Peru) Supreme Decree 029-2015-SA (2015.Sep.11) Article 138	N/A	N/A

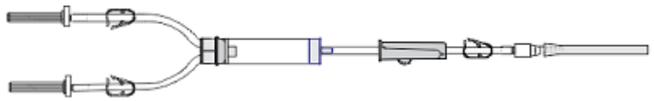
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.					

Code: E5MC4007N

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:



LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.			ISO 8536-11:2015 ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP. Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.42	Labelling shall indicate the date when the medical device was manufactured. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 15223-1:2016 (Brazil) RDC 185 / 2001, Annex III.B 2.5, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 55 f Mexico:: Customs will request even though not official regulation Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (13) (2003) Hong Kong: GN-01, Appendix 3, 2.1e (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3 (l) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.207	Labeling text shall be available in Slovakian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.58	Labelling text shall be available in Czech language.	No	Carton Primary Packaging	Act No. 268/2014 Coll., on medical devices; 22.Oct.2014 Questions on the Use of Medical Devices, September 13, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.118	Labelling text shall be available in Chinese language.	No	Carton Primary Packaging	(for china) Provisions for Medical Device Use Instruction, Labeling and Symbols, No 10 (CFDA), Article 6 No 6: Provisions for IFU and labeling of medical device, Article 9	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.216	Labelling shall contain the Chinese enterprise name in Simplified Chinese.	No	Carton Primary Packaging	(For China) Provisions for Medical Device Use Instruction, Labeling and Symbols, No 10 (CFDA), Article 6 No 6: Provisions for IFU and labeling of medical device, Article 9	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.219	Labelling text shall be available in Slovenian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.220	Labelling text shall be available in Estonian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.225	The Unit Label / Unit Packaging label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.226	The Inner Carton label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.227	The Unit Label / Unit Packaging label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.228	The Carton label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.230	The Unit Label / Unit Packaging label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.231	The carton label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.232	In Unit label / unit packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.233	In carton packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.234	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the AIDC format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.235	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the AIDC format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.236	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the HRI format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.237	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the HRI format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.271	Labelling shall include the year, month and date of expiry, using the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.311	The product shall include a Chinese over-label for China	No	Over Label	China Regulatory Requirements	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

Code: EMC4002A

Description: Single Lead Irrigation Set

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.40	Labelling shall indicate that the set is DEHP plasticized, using the graphical symbol as given in BS EN 15986:2011. Note: Information may be included in insert p.n. 20002430 or symbol definition leaflet.	Yes	Carton Primary Packaging	ISO 15986:2011 MDD (93/42/EEC) Annex I, section 7.5 as amended by 2007/47/EC (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand supply.		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.115	Labelling shall include warnings not to use product if sterility protectors are loose or missing. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MDD (93/42/EEC) Annex I, 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

Code: EMC4015N

Description: Fast Flow Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP. Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand supply.		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

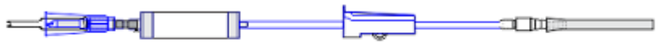
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.130	Labelling shall indicate that the set is non DEHP	Yes	Carton Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.240	Labelling shall Indicate that the irrigation set is non-iv Compatible. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.241	Labelling shall indicate the irrigation set can be used under a maximum allowable pressure of 300mmHg. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.

Code: EMC4042

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

DHF Family: Irrigation Sets

Diagram:



LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP. Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand supply.		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.130	Labelling shall indicate that the set is non DEHP	Yes	Carton Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.225	The Unit Label / Unit Packaging label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.226	The Inner Carton label shall contain a UDI carrier barcode with a UDI-DI and UDI-PI.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 Article 27 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.227	The Unit Label / Unit Packaging label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.228	The Carton label shall include the UDI carrier (AIDC and HRI representation of the UDI) .	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.230	The Unit Label / Unit Packaging label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.231	The carton label shall include the UDI carrier in a readily identifiable manner when AIDC carriers other than the UDI carrier are part of the product labelling.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.232	In Unit label / unit packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.233	In carton packaging the device itself shall include a UDI carrier that shall be readable during normal use, storage, and throughout the intended lifetime of the device.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C 5.5.2017 L 117/119 Official Journal of the European Union EN	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.234	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the AIDC format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.235	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the AIDC format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.236	If there are significant constraints limiting the use of both AIDC and HRI on the Unit Label / Unit Packaging label, only the HRI format shall be required to appear.	Yes	Primary Packaging	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.237	If there are significant constraints limiting the use of both AIDC and HRI on the Carton label, only the HRI format shall be required to appear.	Yes	Carton	MEDICAL DEVICE REGULATION (EU) 2017/745 ANNEX VI PART C	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.240	Labelling shall Indicate that the irrigation set is non-iv Compatible. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.241	Labelling shall indicate the irrigation set can be used under a maximum allowable pressure of 300mmHg. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.

Code: EMC4047

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

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				ISO 8536-11:2015 ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.40	Labelling shall indicate that the set is DEHP plasticized, using the graphical symbol as given in BS EN 15986:2011. Note: Information may be included in insert p.n. 20002430 or symbol definition leaflet.	Yes	Carton Primary Packaging	ISO 15986:2011 MDD (93/42/EEC) Annex I, section 7.5 as amended by 2007/47/EC (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand supply.		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

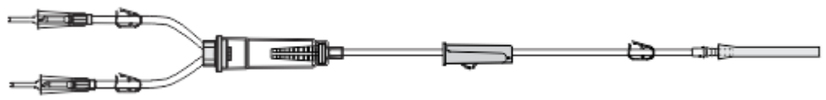
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		

Code: EMC4055N

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

DHF Family: Irrigation Sets

Diagram:



LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.			ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP. Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand supply.		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.130	Labelling shall indicate that the set is non DEHP	Yes	Carton Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.240	Labelling shall Indicate that the irrigation set is non-iv Compatible. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.241	Labelling shall indicate the irrigation set can be used under a maximum allowable pressure of 300mmHg. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.

Code: RMC4916

Description: Irrigation Set

DHF Family: Irrigation Sets

Diagram:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico) Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.40	Labelling shall indicate that the set is DEHP plasticized, using the graphical symbol as given in BS EN 15986:2011. Note: Information may be included in insert p.n. 20002430 or symbol definition leaflet.	Yes	Carton Primary Packaging	ISO 15986:2011 MDD (93/42/EEC) Annex I, section 7.5 as amended by 2007/47/EC (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.66	Labelling shall be printed on primary packaging with blue ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

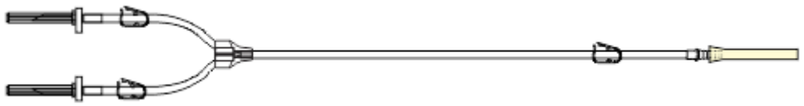
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.115	Labelling shall include warnings not to use product if sterility protectors are loose or missing. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU or symbol definition leaflet.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015 MDD (93/42/EEC) Annex I, 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

Code: VMC4005

Description: Y-Type Irrigation Set

DHF Family: Irrigation Sets

Diagram:



LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.1	Labelling shall include a textual description of the contents. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.55** - Labelling shall include product description.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.3	Labelling shall include an indication that the infusion set is sterile, using the graphical symbol as given in ISO 15223-1. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (c), and 13.3(m); and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (10); 13.4 (3)(11 and 12a) (2003). MEDICAL (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.4	Labelling shall include an indication that the infusion set is free from pyrogens, or that the infusion set is free from bacterial endotoxins.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.			ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013		
MAC-LAR.5	Labelling shall indicate that the set is for single use only. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(f) and 13.6(a), 13.6 (h) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (7); 13.4 (3) (8) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.121** - Where applicable, labelling shall indicate that the set is for single use only.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III, 23.4(s) MDD (93/42/EEC) Annex I, 13.1, 13.3(j) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (1) (c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.51** - I need to identify the directions for use and any cautions of the set **MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate graphical symbol as per ISO 15223-1 may be used.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6) 13.3 (11) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.8	Labelling shall include the year and month of expiry, accompanied by the appropriate graphical symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3 (e) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (12) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.61** - I need to be able to clearly identify the use-by date on the packaging.
MAC-LAR.9	Labelling shall include the name and address of the manufacturer. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 15223-1:2016 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Article 4.a and Annex III.B 2.1, 3.1 (2001); Consumer Protection Decree No 6.523 (15.Jul.2008) RDC 185 / 2001, Annex III (2001) states the requirement for manufacturer. Colombia: Decree no 4725/2005, Article 54 e; 55a (Mexico)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Etiquetado de dispositvos medicos NOM-137-SSA1-2008 Austrailia, New Zealand: Essential Principles for Medical Devices, Principle 13.3 (1), 13.4 (3)(1) (2003) Hong Kong: GN-01, Appendix 3, 2.1a (1.Sep.2005) GN-01, Section 4.4.13b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; ASEAN Medical Device Directive, Version 15, Annex 7; 2013; Notification: Labels and IFU for Medical Devices; Draft Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(a) and 13.6(a); see also MEDDEV 2.1/1 1994 guidance (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.16	Labelling shall include recommended storage conditions, if any.	Yes	Carton Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 MDD (93/42/EEC) Annex I, 13.3(i) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.3 (4); 13.4 (3)(7) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards. **MIT.53** - Where applicable, labelling shall indicate storage and handling conditions.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013 (For India) The Legal Metrology (Packaged Commodities) Rules, 2011 (Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001); Colombia:: Decree no 4725/2005, Article 54 a; 55 c (Mexico) Medical Device Labeling Norm NOM-137-SSA1-2008. 4.1.1.8 (2008) Austrailia, New Zealand:	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				Essential Principles for Medical Devices, Principle 13.3 (3); 13.4 (3) (6) (2003) Hong Kong: GN-01, Appendix 3, 1b, 2.1.b (1.Sep.2005) Thailand: Medical Device Act B.E. 2551 (A.D. 2008), Section 44; Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft EU: MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.3 (3); 13.4 (6) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.38	Labelling shall indicate that the set does not contain any natural rubber latex. The appropriate graphical symbol as per ISO 15223-1 may be used. Notes: 1. Information shall also be included on the carton label. 2. If space on the primary packaging label is limited, the information may be omitted and be included in the IFU. (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	Yes	Primary Packaging	ISO 15223-1:2016 MDD (93/42/EEC) Annex I, 13.2; must conform to EN ISO 15223-1: 2016 (For Argentina) Dispn_ANMAT_2318_Annex III.B 1.4 (2002) (For Brazil) RDC 185 / 2001, Annex III.B 1.4, 3.1 (2001) (For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138, For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140 (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging. **MAC-UNIU.59** - I need to be able to clearly identify if the set contains natural rubber latex or not.
MAC-LAR.39	Labelling shall indicate that the set contains less than 0.1% m/m DEHP.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 15986:2011	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	Note: If the symbol is used and space on the primary packaging label is limited, the definition of the symbol may be omitted and be included in the IFU or symbol definition leaflet.					**MAC-UNIU.58** - I need to be able to clearly identify if the set contains DEHP plasticizer or not.
MAC-LAR.43	Codes for representation of names of languages shall be in compliance to ISO 639-2. This requirement applies to both primary packaging and IFU, as applicable.	Yes	Carton Primary Packaging	ISO 639-2 Baxter internal requirement ISO 639-2/B or ISO 639-2/T (For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	The Medical Devices Regulations 2002 as amended. (For Wales) The Welsh Language Act of 1993. (For Ireland) Labelling of Medical Devices on the Irish Market - http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf (For Australia) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b) (For New Zealand) Due to minimum regulatory requirements for labelling of medical devices in New Zealand and the Australian TGA requirements aligned to EU MDDs and GHTF/IMDRF guidance, product supplied according to Australia GLAM requirements are considered appropriate for New Zealand supply.	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	Law Decree No. 145/2009 Annex I article 5	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.46	Labelling text shall be available in Spanish language.	No	Carton Primary Packaging	Royal Decree 1591/2009 of October 16, which regulates medical devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.47	Labelling text shall be available in French language.	No	Carton Primary Packaging	(France) French Public Health Code Article R5211-20 (Algeria) Not regulated by law Follow CE marked labels, no specific local requirements (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.48	Labelling text shall be available in German language.	No	Carton Primary Packaging	(Germany) German Medical Device Law (Act) Medizinproduktegesetz, MPG), 2011 (Austria) Medizinproduktegesetz, MPG section 9 (Belgium) Royal Order on Medical Devices 18 March 1999 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.49	Labelling text shall be available in Italian language.	No	Carton Primary Packaging	(Italy) MDD 2007/47, implemented with Italian Decree 37/2010 (Switzerland) Ordinance on Medical Devices (MepV); Tarius summary (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.50	Labelling text shall be available in Dutch language.	No	Carton Primary Packaging	(Belgium) Royal Order on Medical Devices 18 March 1999 (Netherlands) Medical Devices Decree, Article 6 (Language Requirement) (EU) The Medical Devices Regulations 2002 as amended	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.51	Labelling text shall be available in Swedish language.	No	Carton Primary Packaging	(Sweden) MPA Provisions No 2011:13 on Amendment to MPA Provisions No 2003:11 on Medical Devices (Finland) ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.52	Labelling text shall be available in Greek language.	No	Carton Primary Packaging	Official Gazettes 2198-B/02.10.2009 (New MEDDEV), 2917-B/02.10.2009 (Active Implantables), 1060-B/10.08.2001 (In-vitro diagnostics)	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.53	Labelling text shall be available in Finnish language.	No	Carton Primary Packaging	ISO 639-1; Act No 629/2010 on Medical Devices	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.54	Labelling text shall be available in Danish language.	No	Carton Primary Packaging	Executive Order no. 1263 of 15.Dec.2008 Danish Medicines Agency No 9823 Guideline on Labeling and User Instructions for Medical Devices, August 22, 2016	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.55	Labelling text shall be available in Norwegian language.	No	Carton Primary Packaging	Regulation No. 1690/2005 on Medical Devices; section 2-6 AIMU I, no. 13,14,15; IVDMU I, part B no. 8 or ØMU (Other Medical Devices) I, no 13	**MIT.38** - Labels shall reflect applicable standards. **MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.60	Labelling shall include Baxter Logo.	Yes	Carton Primary Packaging	Corporate Identity Summary Guide: http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc Baxter's Renal Products Business Brand Guidelines, Supplement to the Corporate Guidelines, May 19, 2015 (Baxter 05 in document library) Baxter Marketing Requirement	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.61	Labelling shall include the CE marking symbol, as per Directive 93/42/EEC Annex XI.	Yes	Carton Primary Packaging	Directive 93/42/EEC Annex XI MDD (93/42/EEC) Article 17 Annex XII, see also European Commission website (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Article 20	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.67	Labelling shall be printed on primary packaging with red ink.	Yes	Primary Packaging	N/A	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.68	Labelling shall indicate the correct location from where to open the primary package.	Yes	Primary Packaging	N/A	**MIT.59** - Where applicable, primary packaging indicates correct location from where to open the package.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is damaged. The appropriate graphical symbol as per ISO 15223-1 may be used. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	ISO 15223-1:2016 ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 ISO 1135-5:2015	**MIT.38** - Labels shall reflect applicable standards.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				MDD (93/42/EEC) Annex I, 13.3 (i) and 13.6 (g) 13.3(k) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter I, 4(C) (For Australia) Essential Principles for Medical Devices, Principle 13.1 (6), 13.4 (3)(12 a, b, c), 13.3 (5); 13.4 (3)(5) (2003) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).		
MAC-LAR.119	Labelling text shall be available in Turkish language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.121	Labelling shall include Country of Origin. Note: If space on the primary packaging label is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007) (For New Zealand) The Medicines Regulations 1984 establish minimum requirements for labelling of medical devices in New Zealand. Medical devices are expected to be labelled in accordance with international best practice. Medsafe recommends that sponsors and manufacturers apply the guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 2016).	**MIT.39** - Labels shall reflect applicable Baxter requirements.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.190	Labeling shall contain the name and address of the importer for Colombia.	No	Carton Primary Packaging	(For Colombia) Decree no 4725/2005, Article 54 e; 55 b; 57	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.192	Labeling shall contain the registration number or marketing permit for Colombia.	No	Carton Primary Packaging	(For Colombia) Decree no 4725/2005, Article 54 d; 57	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.184	Labeling shall contain the registration number preceded by "RS No" or the phrase "Registro sanitario No." for Peru Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	No	Carton Primary Packaging	(For Peru) For packaging: Supreme Decree 029-2015-SA (2015.Sep.11) Article 138 For instructions for use: Supreme decree 016-2011-SA (27.Jul.2011) Article. 140	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.220	Labelling text shall be available in Estonian language.	No	Carton Primary Packaging	N/A	**MIT.58** - Product is required to have legible label.	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.245	Labeling shall contain the name of the importer for Ecuador.	No	Carton Primary Packaging	(For Ecuador) ARCSA-DE-026-2016-YMIH Organic Law of Health, Article 137 and Article 3 of the Rules for registration and sanitary control of devices (1971)	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.246	Labeling shall contain the Health Register number for Ecuador.	No	Carton Primary Packaging	(For Ecuador) Notice 2015-2635 Foreign devices cannot be packaged or labelled locally July 28 2015.	N/A	**MAC-UNIU.52** - I need to be able to read information provided on the product packaging.

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.240	Labelling shall Indicate that the irrigation set is non-iv Compatible. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.241	Labelling shall indicate the irrigation set can be used under a maximum allowable pressure of 300mmHg. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	Yes	Primary Packaging	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.52** - I need to be able to read information provided on the product packaging.
MAC-LAR.243	Labelling shall contain the name and address of the importer or distributor for Peru. Note: If space on the primary packaging is limited, the information may be omitted and be included in the IFU.	No	Primary Packaging	(Peru) Supreme Decree 029-2015-SA (2015.Sep.11) Article 138	N/A	N/A

8 REVISION HISTORY

REVISION	ISSUE DATE	REASON FOR CHANGE
A	Refer to Stamp	New Document
B	Refer to Stamp	As Per Change Control - 2018-001427(PR#1429059) As per Change Control - 2018-005514(PR#1547148)
C	Refer to Stamp	Including previously omitted labelling requirements for irrigation sets as per as per Change Control-2018-005514 (PR 1547148)
D	Refer to Stamp	As Per Change Control-2018-005514(PR# 1547148) As per Change Control-2018-006328(PR# 1572730) As per Change Control-2018-001687(PR# 1435930)
E	Refer to Stamp	As per Change Control-2017-006240 (PR#1367849)
F	Refer to Stamp	Change Control-2020-003710(1909311)
G	Refer to Stamp	Updates as per Change Control-2020-001417(PR#1834273) Updates as per Change Control-2014-006542(PR#376171)
H	Refer to Stamp	Updates as per Change Control-2020-005559 (PR#1971695)
I	Refer to Stamp	Updates as per Change Control-2023-000704 (PR#2576462).
J	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: BXU535428	**Revision ID:** J
Item Name: IRRIGATION SETS (MALTA ACCESS CODES): DESIGN INPUTS - LABELLING 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
Bartolo, Maria	Quality	Document Review - SME & Quality	30-Jan-2025	Approved
Debono, David	SME	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