# 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.

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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.<sup>1</sup>

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BS EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels,	Superseded by: BS EN ISO 15223-1: 2021 (2021-09-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

### 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.

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<sup>&</sup>lt;sup>1</sup> 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:



LARID	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)	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.
				Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)		
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.

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LARID	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	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	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.			ISO 8536-5:2013 ISO 8536-8:2015 ISO 8536-9:2015 ISO 8536-10:2015	standards.	information provided on the product packaging.
				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	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.
				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).		
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) (	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	c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)  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.

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LARID	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		
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	when developing their labelling and instructions for use (23 September 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 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),	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.
				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).		
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.

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LARID	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		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	1998, 2000, 2001, 2003, 2007) ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
				(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)	standards.	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	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.
				MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		ματναβιιιβ.

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LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
LANID	LAN NEQ.	CORE REQ.	PACKAGING TIPE	MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I	IVIII. NEQ.	OIVIO NEQ.
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	·	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
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.	plasticizer or not.  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.

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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 - <a href="http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf">http://www.imb.ie/images/uploaded/documents/Newsletter_Issue10_November2004.pdf</a> (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.

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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/traini_ng/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/download_s/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.

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LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
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	REG 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).  ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 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	MIT. REQ.  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	(23 September 2016).  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
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.	packaging.  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.

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DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

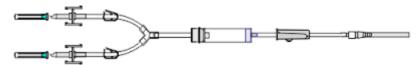
LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
MAC-LAR.222	Labelling text shall be available in Lithuanian language.	No	Carton Primary Packaging	N/A	MIT.58 - Product is required to have legible label.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.
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:



LARID	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	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	(3)(a,b); 13.3 (3) (2003)  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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	,		ISO 8536-10:2015		,
	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	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.
				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).		
MAC-LAR.6	Labelling shall include the instructions for use, including warnings, e.g. about detached protective caps.	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.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
	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		information provided on the product packaging.
				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)		
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.
				MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
2.11.12		301121124	17101010110	MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I		0.1110.112
				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	• • • • • • • • • • • • • • • • • • • •	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	the appropriate graphical symbol as per ISO 15223-1.		Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
				ISO 8536-8:2015		packaging.
				ISO 8536-9:2015 ISO 8536-10:2015		MAC-UNIU.61 - I need to be able to clearly identify the use-by date on the
				ISO 8536-11:2015		packaging.
				ISO 8536-12:2007+A1:2013		packaging.
				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).		
MAC-LAR.9	Labelling shall include the name and address of the manufacturer.	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	The appropriate graphical symbol as per ISO 15223-1 may be used.		Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
				ISO 8536-8:2015 ISO 8536-9:2015		packaging.
	Note: If space on the primary packaging is limited, the information			ISO 8536-10:2015		
	may be omitted and be included in the IFU.			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		
			1	(Mexico)		

DOCUMENT NO: BXU535428 REVISION: J

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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		
		<u> </u>		1998, 2000, 2001, 2003, 2007)		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
				(F. 11) T. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	standards.	information provided on the product packaging.
				(For India) The Legal Metrology (Packaged Commodities)		packagnig.
				Rules, 2011		
				(Descit)		
				(Brazil) RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001);		
				RDC 163 / 2001, Allilex III.B 2.2, 3.1 (2001),		
				Colombia::		
				Decree no 4725/2005, Article 54 a; 55 c		
				Beares 110 4725/2005, 711 tions 54 4, 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;		
				Singaporo		
				Singapore: GN-23 Medical Device Guidance; 2.2.1; May 2014 Draft		
				on 25 Medical Device Galdanice, 2.2.1, May 2014 Dian		
				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,	Yes	Carton	ISO 15223-1:2016	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	including the appropriate symbol as per ISO 15223-1.		Primary Packaging		standards.	information provided on the product
				MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with		packaging.
				Amendments 1998, 2000, 2001, 2003, 2007)		
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I		
				Chapter III		
				(For Australia)		
				(For Australia) Essential Principles for Medical Devices, Principle 13.1 (6),		
				13.3 (3); 13.4 (6) (2003)		
			L	13.3 (3), 13.4 (0) (2003)		<u> </u>

**BAXTER CONFIDENTIAL - INTERNAL USE ONLY** 

PARENT DOCUMENT(S): GQP-09-02 (current rev.)

OWNER CODE: GQC

MAC-UNIU.52 - I need to be able to read

information provided on the product

packaging.

LARID	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	(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;	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.

MIT.38 - Labels shall reflect applicable

MIT.58 - Product is required to have

standards.

legible label.

Yes

Carton

Primary Packaging

Codes for representation of names of languages shall be in

packaging and IFU, as applicable.

compliance to ISO 639-2. This requirement applies to both primary

MAC-LAR.43

(2003)

ISO 639-2

Notification: Labels and IFU for Medical Devices; Draft

Baxter internal requirement ISO 639-2/B or ISO 639-2/T

Essential Principles for Medical Devices, Principle 13.1 (6)

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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/Newslet ter 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.

FORM NO.: **GQT-09-02-01** 

BAXTER DHF NO: 81548-DHF-ERD

DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs - Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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

> PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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ISSUE DATE: 28-DEC-2016 EFFECTIVE DATE: 01-JUL-2017

FORM NO.:

REVISION:

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
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 Yes	Primary Packaging	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).  ISO 8536-4:2010+A1:2013 ISO 8536-9:2015 ISO 8536-9:2015 ISO 8536-12:2007+A1:2013 ISO 1135-4:2015 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	MIT. REQ.  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	No	Primary Packaging	(23 September 2016). 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	may be omitted and be included in the IFU.  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.

FORM NO.: **GQT-09-02-01** 

DOCUMENT NO: BXU535428 REVISION: J

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements EFFECTIVE DATE: SEE STAMP

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	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.
				(For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)		
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 8536-11:2015	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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FORM NO.: **GQT-09-02-01** REVISION: A ISSUE DATE: 28-DEC-2016

LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
LAR ID  MAC-LAR.5	LAR REQ.  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	PACKAGING TYPE Primary Packaging	REG REQ.  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	MIT. REQ.  MIT.38 - Labels shall reflect applicable standards.  MIT.121 - Where applicable, labelling shall indicate that the set is for single use only.	UNIU REQ.  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	guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 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 8536-11:2015 ISO 8536-12:2007+A1:2013	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.
				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)		
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	(2003)  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.
				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		

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	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.
				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).		
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.

DOCUMENT NO: REVISION:	BXU535428 J
EFFECTIVE DATE:	SEE STAMP

LARID	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		
MAC-LAR.16	Labelling shall include recommended storage conditions, if any.	Yes	Carton Primary Packaging	1998, 2000, 2001, 2003, 2007)  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. 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.
				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).		
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)	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.
				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)		

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LARID	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.

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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 - <a href="http://www.imb.ie/images/uploaded/documents/Newsletter-Issue10_November2004.pdf">http://www.imb.ie/images/uploaded/documents/Newsletter-Issue10_November2004.pdf</a> (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.

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

> GQP-09-02 PARENT DOCUMENT(S): (current rev.) OWNER CODE: GOC

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REVISION:

FORM NO.:

ISSUE DATE: 28-DEC-2016 EFFECTIVE DATE: 01-JUL-2017

GQT-09-02-01

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	Yes	Primary Packaging	N/A	MIT.59 - Where applicable, primary	MAC-UNIU.52 - I need to be able to read
	primary package.				packaging indicates correct location	information provided on the product
					from where to open the package.	packaging.
MAC-LAR.114	Labelling shall include warnings not to use product if packaging is	Yes	Primary Packaging	ISO 15223-1:2016	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	damaged. The appropriate graphical symbol as per ISO 15223-1 may			ISO 8536-4:2010+A1:2013	standards.	information provided on the product
	be used.			ISO 8536-5:2013		packaging.
				ISO 8536-8:2015		
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015		
	may be omitted and be included in the IFU.			ISO 8536-10:2015 ISO 8536-11:2015		
				ISO 8536-12:2015		
				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).		
MAC-LAR.121	Labelling shall include Country of Origin.	No	Carton	MDD (93/42/EEC) Annex I, 13.3 (a) (1993, with	MIT.39 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
			Primary Packaging	Amendments 1998, 2000, 2001, 2003, 2007)	Baxter requirements.	information provided on the product
	Note: If space on the primary packaging label is limited, the		, , ,		·	packaging.
	information may be omitted and be included in the IFU.			(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		
NAAC LAD 120	Labelling shall include the ARTMORK decurrent acceptant	Voc	Carton	(23 September 2016).	MIT 20 Labola shall raffeet anniheld	MAC-UNIU.52 - I need to be able to read
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.	information provided on the product
			I IIIIIaiy Fackagilig	Amendments 1990, 2000, 2001, 2003, 2007)	Baster requirements.	packaging.
MAC-LAR.190	Labeling shall contain the name and address of the importer for	No	Carton	(For Colombia)	N/A	MAC-UNIU.52 - I need to be able to read
	Colombia.		Primary Packaging	Decree no 4725/2005, Article 54 e; 55 b; 57	,	information provided on the product
						packaging.
MAC-LAR.192	Labeling shall contain the registration number or marketing permit	No	Carton	(For Colombia)	N/A	MAC-UNIU.52 - I need to be able to read
	for Colombia.		Primary Packaging	Decree no 4725/2005, Article 54 d; 57		information provided on the product
						packaging.
MAC-LAR.184	Labeling shall contain the registration number preceded by "RS No"	No	Carton	(For Peru)	N/A	MAC-UNIU.52 - I need to be able to read
	or the phrase "Registro sanitario No." for Peru		Primary Packaging	For packaging: Supreme Decree 029-2015-SA		information provided on the product
				(2015.Sep.11) Article 138		packaging.
	Note: If space on the primary packaging is limited, the information					
	may be omitted and be included in the IFU.	I	i	For instructions for use:	Ī	i

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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**BAXTER CONFIDENTIAL - INTERNAL USE ONLY** 

REVISION: A

FORM NO.: **GQT-09-02-01** 

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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

Issued Date:30-Jan-2025 Effective Date:30-Jan-2025

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

LARID	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.					

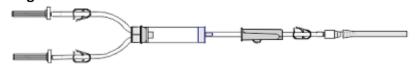
EFFECTIVE DATE: SEE STAMP

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	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	(3)(a,b); 13.3 (3) (2003)  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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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 8536-12.2007+A1:2013 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	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,	Yes	Primary Packaging	when developing their labelling and instructions for use (23 September 2016).  ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.51 - I need to identify the
AINE ENTITO	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.			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	standards.	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.
				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)		
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.
				MDD (93/42/EEC) Annex I, 13.3(d) (1993, with Amendments 1998, 2000, 2001, 2003, 2007)		

LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
	·			MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III		
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	(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).  ISO 8536-4:2010+A1:2013 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 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.  MAC-UNIU.61 - I need to be able to clearly identify the use-by date on the packaging.
				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).		
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)	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

(Mexico)

for manufacturer. Colombia:

Decree no 4725/2005, Article 54 e; 55a

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

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Release Status:Issued and Effective

LARID	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.

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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	(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 (I) 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.

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	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	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.
				(For ANZ) Essential Principles for Medical Devices, Principle 13.1 (6) (2003)		
MAC-LAR.44	Labelling text shall be available in English language.	No	Carton Primary Packaging	(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/Newslet ter_lssue10_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.

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LARID	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/traini_ ng/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/download_s/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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

EFFECTIVE DATE: SEE STAMP

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,	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	Article 9  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 reac 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 reac 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 reac 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 reac 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 reac information provided on the product

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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DOCUMENT NO: BXU535428 REVISION: J

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements EFFECTIVE DATE: SEE STAMP

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.

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	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	(3)(a,b); 13.3 (3) (2003)  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 8536-11:2016  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.

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	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.			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	standards.  MIT.121 - Where applicable, labelling shall indicate that the set is for single use only.	information provided on the product packaging.
				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).		
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,	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.
				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)		
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.
				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		

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ISSUE DATE: 28-DEC-2016 EFFECTIVE DATE: 01-JUL-2017

LARID	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 8536-11:2015 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.  MAC-UNIU.61 - I need to be able to clearly identify the use-by date on the packaging.
				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).		
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.

Release Status:Issued and Effective

LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
LAILID	LANTILY	CONE NEQ.	TACKAGING TIPE	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)	IVIII. NEQ.	ONIO REQ.
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.

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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/Newslet ter 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.

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LARID	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.

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	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.

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FORM NO.: **GQT-09-02-01** REVISION: A

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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		
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	(23 September 2016).  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.

**DHF Family:** Irrigation Sets

Diagram:



LARID	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)	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	Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)  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	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	guidance contained in GHTF/IMDRF guidance documents when developing their labelling and instructions for use (23 September 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	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.

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LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
LANID	LAIT ILEQ	CORE REQ.	TACKAGING TIFE	· ·	Willia NEQ.	SHIO 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 8536-12:2007+A1:2013 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	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	(23 September 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  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.

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FORM NO.: **GQT-09-02-01** REVISION: A

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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	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.
				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).		
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 8536-11:2015 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.
				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	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	Amendments 1998, 2000, 2001, 2003, 2007)  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.

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	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/Newslet ter 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.

**BAXTER CONFIDENTIAL - INTERNAL USE ONLY** 

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	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 reac information provided on the product packaging.

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DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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.

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BAXTER DHF NO: 81548-DHF-ERD

DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs - Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J

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**LARID** 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 ISO 15223-1:2016 MIT.38 - Labels shall reflect applicable MAC-UNIU.52 - I need to be able to read Primary Packaging ISO 15986:2011 standards. 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. Labelling shall Indicate that the irrigation set is non-iv Compatible. MAC-LAR.240 MIT.19 - The set shall include the MAC-UNIU.52 - I need to be able to read Primary Packaging N/A minimum and correct components information provided on the product required to deliver irrigation solution to packaging. Note: If space on the primary packaging is limited, the information urinary drainage catheter and/or may be omitted and be included in the IFU. surgical scope. MAC-LAR.241 MIT.19 - The set shall include the MAC-UNIU.52 - I need to be able to read Labelling shall indicate the irrigation set can be used under a Yes Primary Packaging N/A maximum allowable pressure of 300mmHg. minimum and correct components information provided on the product required to deliver irrigation solution to packaging. urinary drainage catheter and/or Note: If space on the primary packaging is limited, the information surgical scope. may be omitted and be included in the IFU.

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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)	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	Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)  ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 ISO 8536-9:2015 ISO 8536-11:2015 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.

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LARID	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 8536-9:2015 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	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	(23 September 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  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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	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 8536-9:2015 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.

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LARID	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		
MAC-LAR.17	Labelling shall include the number of contained sets.	Yes	Carton	1998, 2000, 2001, 2003, 2007) ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
				(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)	standards.	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.

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

LARID	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 react 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/Newslet ter_lssue10_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.

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EFFECTIVE DATE: SEE STAMP

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
	·			requirements are considered appropriate for New Zealand	,	,
MAC-LAR.45	Labelling text shall be available in Portuguese language.  Labelling text shall be available in Spanish language.	No No	Carton Primary Packaging  Carton	supply.  Law Decree No. 145/2009 Annex I article 5  Royal Decree 1591/2009 of October 16, which regulates	MIT.38 - Labels shall reflect applicable standards. MIT.58 - Product is required to have legible label. MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.  MAC-UNIU.52 - I need to be able to read
			Primary Packaging	medical devices	standards.  MIT.58 - Product is required to have legible label.	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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

Release Status:Issued and Effective

R DHF NO:	81548-DHF-ERD	DOCUMENT NO:	BXU535428
ENT TITLE:	Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements	REVISION:	J
		EFFECTIVE DATE:	SEE STAME

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 8536-5:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 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.

AR 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).		
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.
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.
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.
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.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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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	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	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.
may be omitted and LAR.241 Labelling shall indica maximum allowable  Note: If space on the	the included in the IFU.  Sete the irrigation set can be used under a pressure of 300mmHg.	the included in the IFU.  Sete the irrigation set can be used under a pressure of 300mmHg.  The primary packaging is limited, the information	I be included in the IFU.  Sete the irrigation set can be used under a pressure of 300mmHg.  Per primary packaging is limited, the information	I be included in the IFU.  Set the irrigation set can be used under a pressure of 300mmHg.  Per primary packaging is limited, the information	Urinary drainage catheter and/or surgical scope.  Primary Packaging is limited, the information  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

**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	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.
				(For ANZ) Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)		
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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

FORM NO.: **GQT-09-02-01** 

— D

**BAXTER CONFIDENTIAL - INTERNAL USE ONLY** 

BAXTER DHF NO: 81548-DHF-ERD

DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428
REVISION: J
EFFECTIVE DATE: SEE STAMP

**LARID** LAR REQ. CORE REQ. PACKAGING TYPE **UNIU REQ. REG REQ.** MIT. 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 Yes **Primary Packaging** ISO 8536-4:2010+A1:2013 MIT.38 - Labels shall reflect applicable MAC-UNIU.52 - I need to be able to read information provided on the product appropriate graphical symbol as per ISO 15223-1 may be used. ISO 8536-5:2013 standards. ISO 8536-8:2015 MIT.121 - Where applicable, labelling packaging. ISO 8536-9:2015 shall indicate that the set is for single Note: If space on the primary packaging is limited, the information ISO 8536-10:2015 use only. may be omitted and be included in the IFU. 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). MAC-LAR.6 Labelling shall include the instructions for use, including warnings, Yes **Primary Packaging** ISO 8536-4:2010+A1:2013 MIT.38 - Labels shall reflect applicable MAC-UNIU.51 - I need to identify the e.g. about detached protective caps. ISO 8536-5:2013 standards. directions for use and any cautions of ISO 8536-8:2015 the set ISO 8536-9:2015 MAC-UNIU.52 - I need to be able to read Note: If space on the primary packaging is limited, the information ISO 8536-10:2015 information provided on the product may be omitted and be included in the IFU. ISO 8536-11:2015 packaging. 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) Essential Principles for Medical Devices, Principle 13.1 (1) ( c); Principle 13.2, Principle 13.3 (6); Principle 13.4 (3)(14) (2003)MAC-LAR.7 Labelling shall include the lot (batch) designation. The appropriate ISO 8536-4:2010+A1:2013 MIT.38 - Labels shall reflect applicable MAC-UNIU.52 - I need to be able to read Yes Carton ISO 8536-5:2013 graphical symbol as per ISO 15223-1 may be used. **Primary Packaging** standards. information provided on the product ISO 8536-8:2015 packaging. 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)

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
.=		1- 4		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	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.
				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		
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	(23 September 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 8536-11:2015 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.
				(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)		

DOCUMENT NO: BXU535428 REVISION: J

REVISION: J
EFFECTIVE DATE: SEE STAMP

LARID	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	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	Amendments 1998, 2000, 2001, 2003, 2007)  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.

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FORM NO.: **GQT-09-02-01**REVISION: **A**ISSUE DATE: **28-DEC-2016** 

ISSUE DATE: 28-DEC-2016
EFFECTIVE DATE: 01-JUL-2017

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

LARID	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/Newslet ter 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.

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

FORM NO.: **GQT-09-02-01** REVISION: A

> ISSUE DATE: 28-DEC-2016 EFFECTIVE DATE: 01-JUL-2017

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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: <a href="http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf">http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf</a> Baxter Corporate Proper Labeling Quick Reference Guide: <a href="http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc">http://corporate.inbaxter.com/law/trademarks/downloads/labelingquickref.doc</a> 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 8536-11:2015 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.

Issued Date:30-Jan-2025 Effective Date:30-Jan-2025

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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).

Release Status:Issued and Effective

OWNER CODE: GQC

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)	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	Essential Principles for Medical Devices, Principle 13.1 (3)(a,b); 13.3 (3) (2003)  ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 ISO 8536-9:2015 ISO 8536-11:2015 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.

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PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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	331121124	171010101110	ISO 8536-10:2015		0111011124
	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	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	appropriate graphical symbol as per ISO 15223-1 may be used.			ISO 8536-5:2013	standards.	information provided on the product
				ISO 8536-8:2015	MIT.121 - Where applicable, labelling	packaging.
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015	shall indicate that the set is for single	
	may be omitted and be included in the IFU.			ISO 8536-10:2015	use only.	
				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		
				Chapter III		
				(For Australia)		
				Essential Principles for Medical Devices, Principle 13.1 (6),		
1				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).		
MAC-LAR.6	Labelling shall include the instructions for use, including warnings,	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.51 - I need to identify the
	e.g. about detached protective caps.			ISO 8536-5:2013 ISO 8536-8:2015	standards.	directions for use and any cautions of the set
				ISO 8536-9:2015		MAC-UNIU.52 - I need to be able to read
	Note: If space on the primary packaging is limited, the information			ISO 8536-10:2015		information provided on the product
	may be omitted and be included in the IFU.			ISO 8536-11:2015		packaging.
				ISO 8536-12:2007+A1:2013		P. 2. 1.0.1.0.1
				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)		
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	graphical symbol as per ISO 15223-1 may be used.		Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
1	,			ISO 8536-8:2015		packaging.
				ISO 8536-9:2015		
1				ISO 8536-10:2015		
1				ISO 8536-11:2015		
1				ISO 8536-12:2007+A1:2013		
1				ISO 15223-1:2016		
1				MDD (93/42/EEC) Annex I, 13.3(d) (1993, with		
				Amendments 1998, 2000, 2001, 2003, 2007)		

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LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
2 11(12	2 1124.	3311211241	17.0.0.10.11.1	MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I		5.11.5 1.1.2.
				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	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	the appropriate graphical symbol as per ISO 15223-1.		Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
				ISO 8536-8:2015		packaging.
				ISO 8536-9:2015		MAC-UNIU.61 - I need to be able to
				ISO 8536-10:2015		clearly identify the use-by date on the
				ISO 8536-11:2015		packaging.
				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).		
MAC-LAR.9	Labelling shall include the name and address of the manufacturer.	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	The appropriate graphical symbol as per ISO 15223-1 may be used.		Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
				ISO 8536-8:2015		packaging.
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015 ISO 8536-10:2015		
	may be omitted and be included in the IFU.			ISO 8536-10.2015		
				ISO 8536-12:2013		
				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)		

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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		
MAC-LAR.17	Labelling shall include the number of contained sate	Vos	Carton	1998, 2000, 2001, 2003, 2007) ISO 8536-4:2010+A1:2013	MIT 29 Labole chall reflect applies to	MAC LINIULES. I pood to be able to read
IVIAC-LAK.1/	Labelling shall include the number of contained sets.	Yes	Carton	13U 0330-4:2U1U+A1:2U13	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product
				(For India) The Legal Metrology (Packaged Commodities)		packaging.
				Rules, 2011		
				(Brazil)		
				RDC 185 / 2001, Annex III.B 2.2, 3.1 (2001);		
				Colombia:: Decree no 4725/2005, Article 54 a; 55 c		
				Decree 110 4723/2003, Article 34 a, 33 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;		
				Micarcal Device Act B.E. 2001 ( A.D. 2000), 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,	Yes	Carton	ISO 15223-1:2016	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	including the appropriate symbol as per ISO 15223-1.		Primary Packaging		standards.	information provided on the product
				MDD (93/42/EEC) Annex I, 13.3(b) and 13.6(a) (1993, with		packaging.
				Amendments 1998, 2000, 2001, 2003, 2007)		
				MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I Chapter III		
				Chapter III		
				(For Australia)		
				Essential Principles for Medical Devices, Principle 13.1 (6),		
				13.3 (3); 13.4 (6) (2003)		

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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/Newslet ter 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.

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FORM NO.: **GQT-09-02-01** REVISION: A

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MAC-UNIU.52 - I need to be able to read

information provided on the product

packaging.

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LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
				requirements are considered appropriate for New Zealand		
MAC-LAR.45	Labelling text shall be available in Portuguese language.	No	Carton Primary Packaging	supply.  Law Decree No. 145/2009 Annex I article 5	MIT.38 - Labels shall reflect applicable standards. MIT.58 - Product is required to have	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	legible label.  MIT.38 - Labels shall reflect applicable standards.  MIT.58 - Product is required to have	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	legible label.  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.
		1	I a .	Description No. 1000/2005 on Madical Devices, costion 2.0		

PARENT DOCUMENT(S): GQP-09-02 (current rev.)

Labelling text shall be available in Norwegian language.

MAC-LAR.55

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

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standards.

legible label.

MIT.38 - Labels shall reflect applicable

MIT.58 - Product is required to have

FORM NO.: **GQT-09-02-01** 

No

Carton

Primary Packaging

LARID	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.

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EFFECTIVE DATE: SEE STAMP

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.

EFFECTIVE DATE: SEE STAMP

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	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	(3)(a,b); 13.3 (3) (2003)  ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 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.

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DOCUMENT NO: BXU535428

REVISION:	J
EFFECTIVE DATE:	SEE STAMP

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 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 ISO 8536-9:2015 ISO 8536-11:2015 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	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	(23 September 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  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 8536-11:2015 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.

DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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)	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.
				(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).		
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	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product packaging.
				(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:		

LARID	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	(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	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	Amendments 1998, 2000, 2001, 2003, 2007)  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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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ISSUE DATE: 28-DEC-2016 EFFECTIVE DATE: 01-JUL-2017

DOCUMENT NO: BXU535428 REVISION: J

EFFECTIVE DATE: SEE STAMP

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/Newslet ter 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.

Release Status:Issued and Effective

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/traini_ng/guide_summary_online.pdf Baxter Corporate Proper Labeling Quick Reference Guide: http://corporate.inbaxter.com/law/trademarks/download_s/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.

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	LAR REO	CORE REO	PACKAGING TYPE	REG REO	MIT REO	LINILI REO
LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG 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	MIT. REQ.	UNIU REQ.
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 8536-5:2015 ISO 8536-9:2015 ISO 8536-10:2015 ISO 8536-11:2015 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	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	(3)(a,b); 13.3 (3) (2003)  ISO 8536-4:2010+A1:2013 ISO 8536-5:2013 ISO 8536-9:2015 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.

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LARID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	Mit. Req.	UNIU REQ.
	Note: If space on the primary packaging is limited, the information			ISO 8536-10:2015		
	may be omitted and be included in the IFU.			ISO 8536-11:2015		
MACLARE	I alkalling shall indicate that the eat is fau single use sulv. The	Vee	Daimen Deelineine	ISO 8536-12:2007+A1:2013	NAIT 20. Labala aball rafta et annicable	NACCHNILLES I wood to be oble to good
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.	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013 ISO 8536-5:2013	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product
	appropriate graphical symbol as per 150 15225-1 may be used.			ISO 8536-8:2015	MIT.121 - Where applicable, labelling	packaging.
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015	shall indicate that the set is for single	p-1-1-66.
	may be omitted and be included in the IFU.			ISO 8536-10:2015	use only.	
				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).		
MAC-LAR.6	Labelling shall include the instructions for use, including warnings,	Yes	Primary Packaging	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.51 - I need to identify the
	e.g. about detached protective caps.			ISO 8536-5:2013	standards.	directions for use and any cautions of
				ISO 8536-8:2015		the set
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015		MAC-UNIU.52 - I need to be able to read
	may be omitted and be included in the IFU.			ISO 8536-10:2015 ISO 8536-11:2015		information provided on the product packaging.
				ISO 8536-12:2015		packaging.
				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)		
MAC-LAR.7	Labelling shall include the lot (batch) designation. The appropriate	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
	graphical symbol as per ISO 15223-1 may be used.		Primary Packaging	ISO 8536-5:2013 ISO 8536-8:2015	standards.	information provided on the product packaging.
				ISO 8536-9:2015		kaa.mpp.
				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		
		1	l	Amendments 1998, 2000, 2001, 2003, 2007)		

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

LAR ID	LAR REQ.	CORE REQ.	PACKAGING TYPE	REG REQ.	MIT. REQ.	UNIU REQ.
2,11,12	22	3011211241	171010101101112	MEDICAL DEVICE REGULATION (EU) 2017/745 Annex I		
				Chapter III		
				- 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		
NAAC LAD O	Labelline shell include the consumant of soming assessmented by	Vaa	Conton	(23 September 2016).	BAIT 20 Labala shall yaflaat ayalisahla	NAAC UNUU F2 I waad ta ba abla ta waa
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	MIT.38 - Labels shall reflect applicable standards.	MAC-UNIU.52 - I need to be able to read information provided on the product
	the appropriate graphical symbol as per 130 13223-1.		Filliary Fackaging	ISO 8536-8:2015	Standards.	packaging.
				ISO 8536-9:2015		MAC-UNIU.61 - I need to be able to
				ISO 8536-10:2015		clearly identify the use-by date on the
				ISO 8536-11:2015		packaging.
				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).		
MAC-LAR.9	Labelling shall include the name and address of the manufacturer.	Yes	Carton	ISO 8536-4:2010+A1:2013	MIT.38 - Labels shall reflect applicable	MAC-UNIU.52 - I need to be able to read
WIAC-LAIN.5	The appropriate graphical symbol as per ISO 15223-1 may be used.	163	Primary Packaging	ISO 8536-5:2013	standards.	information provided on the product
	appropriate 8. aprilled: 57		la., . asiaging	ISO 8536-8:2015	513.1143.145.	packaging.
	Note: If space on the primary packaging is limited, the information			ISO 8536-9:2015		P
	may be omitted and be included in the IFU.			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)		
			<u> </u>	(MICNICO)		

PARENT DOCUMENT(S): GQP-09-02 (current rev.) OWNER CODE: GQC

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 81548-DHF-ERD Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements	DOCUMENT NO: REVISION:	BXU535428 J
	EFFECTIVE DATE:	SEE STAMP

LARID	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.

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428
REVISION: J

EFFECTIVE DATE: SEE STAMP

LARID	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		
MAC-LAR.37	Labelling shall indicate the manufacturer's catalogue number, including the appropriate symbol as per ISO 15223-1.	Yes	Carton Primary Packaging	Amendments 1998, 2000, 2001, 2003, 2007)  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.

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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/Newslet ter_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.

Release Status:Issued and Effective

BAXTER DHF NO: 81548-DHF-ERD
DOCUMENT TITLE: Irrigation Sets (Malta Access Codes): Design Inputs – Labelling Requirements

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

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: <a href="http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf">http://corporate.inbaxter.com/corp_id/documents/training/guide_summary_online.pdf</a> Baxter Corporate Proper Labeling Quick Reference Guide: <a href="http://corporate.inbaxter.com/law/trademarks/download-s/labelingquickref.doc">http://corporate.inbaxter.com/law/trademarks/download-s/labelingquickref.doc</a> 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.

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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		
MAC-LAR.119	Labelling text shall be available in Turkish language.	No	Carton	(23 September 2016). N/A	MIT.58 - Product is required to have	MAC-UNIU.52 - I need to be able to read
			Primary Packaging		legible label.	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.

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LARID	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

DOCUMENT NO: BXU535428 REVISION: J EFFECTIVE DATE: SEE STAMP

# 8 REVISION HISTORY

REVISION	ISSUE DATE	Reason for Change
А	Refer to Stamp	New Document
В	Refer to Stamp	As Per Change Control - 2018-001427(PR#1429059) As per Change Control - 2018-005514(PR#1547148)
С	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)
Е	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)
Н	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.

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## **TcU ELECTRONIC SIGNATURE REPORT**

REVISION INFORMATION					
Item ID: BXU535428	Revision ID: J				
Item Name: IRRIGATION SETS (MALTA ACCESS	Release Date: 30-Jan-2025				
CODES): DESIGN INPUTS - LABELLING					
REQUIREMENTS					
Description:					

**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):

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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		

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