



Declaration of Conformity

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Technical File: **TF-107**

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name: **Enteral Feeding Pumps, Feeding Sets & Accessories**

Manufacturer: **Covidien Inc
15 Hampshire Street
Mansfield, MA. 02048 USA**

EC Representative: **Covidien Ireland Limited
IDA Business and Technology Park
Tullamore**



Intended Use: The Kangaroo Connect, ePump, Joey pumps, Feeding Sets and accessories, are intended to be used on patients (both ambulatory and non-ambulatory) with conditions requiring enteral feeding and/or hydration; this is accomplished by delivering enteral nutrition at a controlled rate to a patients gastrointestinal system.

Sterility: No *Refer to Attached Table*

Measuring Function: Yes and No (Measurement items denoted with * on product list)

Directive Classification: I (non-sterile) and IIa

In Accordance with Annex: VII and II

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principals, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S. and follow conformity assessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Date CE Marking Approved: *Refer to Attached Table*

Current Standards to which Conformity is declared: *Refer to Attached Table*

Reorder codes/GMDN Codes: *Refer to Attached Table*

EC Certificate(s): *Refer to Attached Table*

Notified Body Name: TÜV SÜD Product Service GmbH
Ridlerst 65
D-80339 München, Germany

Identification Number: 0123

Signature:

Alexis Erazo, Sr. Regulatory Affairs Specialist

17-Aug-2017
Date

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
1814717995	Kangaroo™ 3-in-1 Adaptor	EO	Enteral feeding kit [11677]	2	03/25/2011
382400*	Kangaroo™ Epump Enteral Feed and Flush Pump with Pole Clamp, Programmable	Non	Infusion pump, enteral feeding [13209]	11	11/30/2005
382400W*	Kangaroo™ Epump Enteral Feed and Flush Pump with Pole Clamp, Programmable	Non	Infusion pump, enteral feeding [13209]	11	3/1/2009
382401*	Kangaroo™ Epump Enteral Feed and Flush Pump with Pole Clamp, Programmable Refurbished	Non	Infusion pump, enteral feeding [13209]	11	11/30/2005
382491	Kangaroo™ Epump Power Cord	Non	Electrical mains power cable [45804]	11	2/1/2005
382493	Kangaroo™ Epump Power Adapter Plug	Non	Electrical mains power cable [45804]	11	2/1/2005
383400*	Kangaroo™ Joey Enteral Feed and Flush Pump with Pole Clamp	Non	Infusion pump, enteral feeding [13209]	11	11/13/2006

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EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
383400W	Kangaroo™ Joey Enteral Feed and Flush Pump with Pole Clamp, Programmable	Non	Infusion pump, enteral feeding [13209]	11	3/17/2010
383401*	Kangaroo™ Joey Enteral Feed Pump W/Pole Clamp, Programmable Refurbished	Non	Infusion pump, enteral feeding [13209]	11	11/13/2006
383491	Kangaroo™ Joey Power Cord	Non	Electrical mains power cable [45804]	11	11/13/2006
384494	Kangaroo™ Connect Car Charger	Non	External battery charger [17115]	11	04/27/2016
482400*	Kangaroo™ Epump Enteral Feed and Flush Pump with Pole Clamp, Programmable	Non	Infusion pump, enteral feeding [13209]	11	2/1/2005
482400J*	Kangaroo™ Epump Enteral Feed and Flush Pump with Pole Clamp, Programmable	Non	Infusion pump, enteral feeding [13209]	11	3/27/2013
482400S*	Kangaroo™ Epump Enteral Feed and Flush Pump, Programmable	Non	Infusion pump, enteral feeding [13209]	11	1/12/2009

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EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
584400*	Kangaroo™ Connect Enteral Feeding Pump	Non	Infusion pump, enteral feeding [13209]	11	8/21/2014
612054	Kangaroo™ Epump Set, 500 mL	ETO	Enteral feeding kit [11677]	2	2/1/2005
613650	Kangaroo™ Epump Enteral Feeding 1000ML SET – Sterile	ETO	Enteral feeding kit [11677]	2	2/1/2005
614650	Kangaroo™ Epump Set, Proximal Spike	ETO	Enteral feeding kit [11677]	2	2/1/2005
6660157	Kangaroo™ Joey Vented Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011
6660317	Kangaroo™ Joey Long Safe-T Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011
6660567	Kangaroo™ Joey Burette Set, Male Luer Y-port, 100 mL	EO	Enteral feeding kit [11677]	2	03/25/2011

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Class IIa Annex II					
666064	Kangaroo™ Joey Pump Set, 500 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6660647	Kangaroo™ Joey Pump Set, Male Luer Y-port, 500 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
666106	Kangaroo™ Joey Pump Set, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6661067	Kangaroo™ Joey Pump Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6661637	Kangaroo™ Joey Pump Set, Male Luer Y-port, 1600 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6680137	Kangaroo™ Joey Universal Spike Feed and Vented Spike Flush Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011
6680217	Kangaroo™ Joey Safety Spike Long Feed and Flush Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011

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Class IIa Annex II					
668104	Kangaroo™ Joey Feed and Flush Set, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6681047	Kangaroo™ Joey Feed and Flush Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6683107	Kangaroo™ Joey 3-in-1 Feed and Flush Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
6683117	Kangaroo™ Joey 3-in-1 Feed and Flush Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
672055	Kangaroo™ Epump Set Anti-free Flow 500 mL	Non	Enteral feeding kit [11677]	2	2/1/2005
673656	Kangaroo™ Epump Set Anti-free Flow 1000 mL	Non	Enteral feeding kit [11677]	2	2/1/2005
673662	Kangaroo™ Epump Set with Flush Bag Anti-free Flow 1000 mL	Non	Enteral feeding kit [11677]	2	2/1/2005

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Class IIa Annex II					
674655	Kangaroo™ Epump Proximal Spike Set Anti-free Flow	Non	Enteral feeding kit [11677]	2	2/1/2005
674668	Kangaroo™ Epump and Joey Pump Set with Flush Bag, Anti-free Flow, 500 mL	Non	Enteral feeding kit [11677]	2	8/28/2007
674669	Kangaroo™ Epump Proximal Spike Set with Flush Bag Anti-free Flow 1000 mL	Non	Enteral feeding kit [11677]	2	2/1/2005
676250	Kangaroo™ Epump and Joey Rigid Container Pump Set Anti-free Flow 1200 mL	Non	Enteral feeding kit [11677]	2	2/1/2005
676255	Kangaroo™ Epump and Joey Rigid Container Pump Set Anti-free Flow 600 mL	Non	Enteral feeding kit [11677]	2	2/1/2005
762055	Kangaroo™ Joey Pump Set, Anti-free Flow, 500 mL	Non	Enteral feeding kit [11677]	2	11/11/2008
763656	Kangaroo™ Joey Pump Set, Anti-free Flow, 1000 mL	Non	Enteral feeding kit [11677]	2	11/11/2008

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Class IIa Annex II					
763662	Kangaroo™ Joey Pump Set with Flush Bag, Anti-free Flow, 1000 mL	Non	Enteral feeding kit [11677]	2	11/11/2008
765100	Kangaroo™ Joey Safety Screw Spike with Flush Bag, Anti-free Flow,1000 mL	Non	Enteral feeding kit [11677]	2	5/1/2012
765555	Kangaroo™ Joey Safety Screw Spike Set, Anti-free Flow	Non	Enteral feeding kit [11677]	2	11/11/2008
765559	Kangaroo™ Joey Safety Screw Spike Set, Anti-free Flow	Non	Enteral feeding kit [11677]	2	5/1/2012
765662	Kangaroo™ Joey Safety Screw Spike with Flush Bag, Anti-free Flow, 1000 mL	Non	Enteral feeding kit [11677]	2	11/11/2008
77000FD	Kangaroo™ Connect ENPlus Spike Set Anti-free Flow	Non	Enteral feeding kit [11677]	2	07/29/2015
77100FD	Kangaroo™ Connect Feeding Set Anti-free Flow 1000 mL	Non	Enteral feeding kit [11677]	2	07/29/2015

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EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
77500FD	Kangaroo™ Connect Feeding Set Anti-free Flow 500 mL	Non	Enteral feeding kit [11677]	2	07/29/2015
775100	Kangaroo™ Epump Safety Screw Spike with Flush Bag, Anti-free Flow, 1000 mL	Non	Enteral feeding kit [11677]	2	5/1/2012
775659	Kangaroo™ Epump Safety Screw Spike Set, Anti-free Flow	Non	Enteral feeding kit [11677]	2	5/1/2012
775759	Kangaroo™924 Safety Screw Spike Set	Non	Enteral feeding kit [11677]	2	5/1/2012
776150*	Kangaroo™ Epump and Joey Burette Recertification Set 100 mL	Non	Enteral feeding kit [11677]	2	7/23/2004
7770157	Kangaroo™ Epump Vented Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011
7770317	Kangaroo™ Epump Safety Spike Long Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	03/25/2011

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Class IIa Annex II					
777056	Kangaroo™ Epump Burette Set, Anti-free Flow, 100 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
7770567	Kangaroo™ Epump Burette Set, Male Luer Y-port, 100 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
777064	Kangaroo™ Epump Easy Cap Pump Set, Anti-free Flow, 500 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
7770647	Kangaroo™ Epump Set, Male Luer Y-port, 500 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
777106	Kangaroo™ Epump Easy Cap Pump Set, Anti-free Flow, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
7771067	Kangaroo™ Epump Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
777163	Kangaroo™ Epump Easy Cap Pump Set, Anti-free Flow, 1600 mL	EO	Enteral feeding kit [11677]	2	03/25/2011

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EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa					
Annex II					
777401	Kangaroo™ Epump ENPlus Spike Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7774017	Kangaroo™ Epump ENPlus Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013
777402	Kangaroo™ Epump Dual ENPlus Spike Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7774027	Kangaroo™ Epump Dual ENPlus Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013
777403	Kangaroo™ Epump ENPlus 3-in-1 Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7774037	Kangaroo™ Epump ENPlus 3-in-1 Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013
777405	Kangaroo™ Epump ENPlus Spike Feed and Flush Bag, 1000mL	EO	Enteral feeding kit [11677]	2	1/18/2013

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Class IIa Annex II					
7774057	Kangaroo™ Epump ENPlus Spike Feed and Flush Bag, Male Luer Y-port, 1000mL	EO	Enteral feeding kit [11677]	2	1/18/2013
777406	Kangaroo™ Epump ENPlus 3-in-1 Feed and Flush Bag, 1000mL	EO	Enteral feeding kit [11677]	2	1/18/2013
7774067	Kangaroo™ Epump ENPlus 3-in-1 Feed and Flush Bag, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	1/18/2013
777407	Kangaroo™ Epump ENPlus Spike Feed and Vented Spike Flush Set	EO	Enteral feeding kit [11677]	2	1/18/2013
777408	Kangaroo™ Epump ENPlus 3-in-1 Feed and Flush Set	EO	Enteral feeding kit [11677]	2	1/18/2013
777501	Kangaroo™ Joey ENPlus Spike Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7775017	Kangaroo™ Joey ENPlus Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013

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Class IIa Annex II					
777502	Kangaroo™ Joey Dual ENPlus Spike Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7775027	Kangaroo™ Joey Dual ENPlus Spike Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013
777503	Kangaroo™ Joey ENPlus 3-in-1 Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7775037	Kangaroo™ Joey ENPlus 3-in-1 Set, Male Luer Y-port	EO	Enteral feeding kit [11677]	2	1/18/2013
777505	Kangaroo™ Joey ENPlus Spike Feed and Flush Bag, 1000 mL	EO	Enteral feeding kit [11677]	2	1/18/2013
7775057	Kangaroo™ Joey ENPlus Spike Feed and Flush Bag, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	1/18/2013
777506	Kangaroo™ Joey ENPlus 3-in-1 Feed and Flush Bag, 1000 mL	EO	Enteral feeding kit [11677]	2	1/18/2013

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EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
777507	Kangaroo™ Joey ENPlus Spike Feed and Vented Spike Flush Set	EO	Enteral feeding kit [11677]	2	1/18/2013
7780137	Kangaroo™ Epump Universal Spike Feed and Vented Spike Flush Set	EO	Enteral feeding kit [11677]	2	03/25/2011
778021	Kangaroo™ Epump Safety Spike Long Feed and Flush Set	EO	Enteral feeding kit [11677]	2	03/25/2011
778104	Kangaroo™ Epump Feed and Flush Bag, Anti-free Flow, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
7781047	Kangaroo™ Epump Feed and Flush Set, Male Luer Y-port, 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
778161	Kangaroo™ Epump Feed and Flush Bag, 1600 mL/1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011
7781617	Kangaroo™ Epump Feed and Flush Set, Male Luer Y-port, 1600 mL / 1000 mL	EO	Enteral feeding kit [11677]	2	03/25/2011

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: G1 14 11 74735 015 expires 23-Feb-2020					
Class IIa Annex II					
970000FD	Kangaroo™ Connect Universal Spike Feeding Set Anti-free Flow	EO	Enteral feeding kit [11677]	2	8/21/2014
970157FD	Kangaroo™ Connect Vented Spike Set, Anti-free Flow	EO	Enteral feeding kit [11677]	2	8/21/2014
970497FD	Kangaroo™ Connect Dual Universal Spike Set, Anti-free Flow	EO	Enteral feeding kit [11677]	2	8/21/2014
970500FD	Kangaroo™ Connect Feeding Set with Bag, Anti-free Flow, 500 mL	EO	Enteral feeding kit [11677]	2	8/21/2014
971000FD	Kangaroo™ Connect Feeding Set with Bag, Anti-free Flow, 1000 mL	EO	Enteral feeding kit [11677]	2	8/21/2014
971600FD	Kangaroo™ Connect Feeding Set with Bag, Anti-free Flow, 1600 mL	EO	Enteral feeding kit [11677]	2	8/21/2014

EC Certificate: Self Certified

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>					
Class I (non-sterile) Annex VII					
382492	Kangaroo™ Epump Pole Clamp	Non	Enteral feeding pole [60715]	1	7/23/2004
382494	Kangaroo™ Epump Power Cord Retaining Clip	Non	Electrical mains power cable [45804]	1	11/16/2006
382499	Kangaroo™ Epump Communication Cable	Non	Electrical-only medical device connection cable, reusable [47487]	1	11/16/2006
383493	Kangaroo™ Joey Pole Clamp	Non	Enteral feeding pole [60715]	1	11/13/2006
384492	Kangaroo™ Connect Pole Clamp	Non	Enteral feeding pole [60715]	1	8/21/2014
584491	Kangaroo™ Connect Power Cord, Contains European, UK and Australian Adapters	Non	Electrical mains power cable [45804]	1	8/21/2014
770025	Kangaroo™ Joey Black Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified					
Class I (non-sterile) Annex VII					
770026	Kangaroo™ Joey Blue Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770027	Kangaroo™ Joey Green Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770028	Kangaroo™ Joey Blue Super Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770029	Kangaroo™ Joey Pink Super Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770031	Kangaroo™ Joey Black Super Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770032	Kangaroo™ Joey Green Super Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009
770034	Kangaroo™ Joey Pink Mini Backpack	Non	Bag, medical device, reusable [37685]	1	05/04/2009

Products Covered By This Certificate

Reorder Code	Description	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: Self Certified					
Class I (non-sterile) Annex VII					
770035M	Kangaroo™ Connect Value Backpack Purple Medium	Non	Bag, medical device, reusable [37685]	1	3/24/2017
770035S	Kangaroo™ Connect Value Backpack Purple small	Non	Bag, medical device, reusable [37685]	1	3/24/2017
770037M	Kangaroo™ Connect Value Backpack Black Medium	Non	Bag, medical device, reusable [37685]	1	3/24/2017
770037S	Kangaroo™ Connect Value Backpack Black small	Non	Bag, medical device, reusable [37685]	1	3/24/2017

Standards to Which Conformity is Declared:

Standard Name:	Standard Title:	Version:
EN 1615:2000	Enteral Feeding Catheters And Enteral Giving Sets For Single Use And Their Connectors - Design And Testing	2000
EN 1618:1997	Catheters Other Than Intravascular Catheters - Test Methods For Common Properties	1997
EN 556-1:2001/AC:2006	Sterilization Of Medical Devices - Requirements For Medical Devices To Be Designated "Sterile" - Part 1: Requirements For Terminally Sterilized Medical Devices	2001 COR 1 2006
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice	2011
ISO 11135-1:2007	Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices	1 ED 2007
EN ISO 11607-1: 2006	Packaging for Terminally Sterilized Medical Devices -- Part 1: Requirements for materials, Sterile Barrier Systems and Packaging Systems.	2006
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices	2008
EN ISO 11607-2: 2006	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirments for Forming, Sealing and Assembly Processes	1 ED 2006
ISO 10993-7:2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2ED 2008

Unless otherwise indicated, full conformance to listed standards is assumed.

Standard Name:	Standard Title:	Version:
EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	AMD 11, 2011
EN 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance. Collateral Standard: Electromagnetic Compatability - Requirements and Tests	2007 (COR 2010)
EN 60601-1-8:2007/A1:2013	Medical Electrical Equipment - Part 1-8: General Requirements for Safety - Collateral Standard: General Requirements, Tests, and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical systems	2007
ISO 10993-1:2009	ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009
ISTA 2A	ISTA Preshipment Testing Procedures - Combination tests for packaged products weighing 150lbs (68kg) or less	2011
EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	2012/AC:2012
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices	2012
EN ISO 15223-1:2012	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements	2012
EN 62304	Medical device software - Software life-cycle processes	2006
EN 62366	Medical devices - Application of usability engineering to medical devices	2008

Unless otherwise indicated, full conformance to listed standards is assumed.

Standard Name:	Standard Title:	Version:
EN 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environmen	2010
ISO/IEC DIS.2 80369-3	Small-bore connectors for liquids and gasses in healthcare application - Part 3: Connectors for enteral applications	2014-07-18
ISO 11135-1:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	2014

Unless otherwise indicated, full conformance to listed standards is assumed.