Essential Requirements Checklist

Silicone Prostatic Catheter

CONTENT

Introduction

Essential requirements checklist for the principles of safety and performance and Coloplast documentation for:

EC Declaration of Conformity Product name	PDT/DHF overview
X-FLOW® STRAIGHT Prostatectomy catheter / 3-way / silicone REF.: AB6018, AB6020, AB6022, AB6024 X-FLOW® Couvelaire Prostatectomy catheter / 3-way / silicone REF.: AB6118, AB6120, AB6122, AB6124 X-FLOW® Delinotte Prostatectomy catheter / 3-way / silicone REF.: AB6218, AB6220, AB6222, AB6224 X-FLOW® Dufour Prostatectomy catheter / 3-way / silicone REF.: AB6318, AB6320, AB6322, AB6324 X-FLOW® Dufour Prostatectomy catheter / 2-way / silicone REF.: AB6418, AB6420, AB6422, AB6424 X-FLOW® Couvelaire Prostatectomy catheter / 2-way / silicone REF.: AB6518, AB6520, AB6522, AB6524 X-FLOW® Dufour Prostatectomy catheter / 3-way / silicone REF.: AB6A18, AB6A20, AB6A22, AB6A24 X-FLOW® Couvelaire Prostatectomy catheter / 3-way / silicone REF.: AB6B18, AB6B20, AB6B22, AB6B24 X-FLOW® Straight Prostatectomy catheter / 3-way / silicone REF.: AB6C18, AB6C20, AB6C22, AB6C24 X-FLOW® Delinotte Prostatectomy catheter / 3-way / silicone REF.: AB6E18, AB6E20, AB6E22, AB6E24 X-FLOW® Prostatectomy short catheter over the guide / 3-way / silicone REF.: AB6G18, AB6G20, AB6G22, AB6G24 X-FLOW® Prostatectomy short catheter straight / 3-way / silicone REF.: AB6H18, AB6H20, AB6H22, AB6H24 X-FLOW® Prostatectomy short catheter straight / 3-way / silicone REF.: AB6J18, AB6J20, AB6J22, AB6J24 X-FLOW® Dufour Prostatectomy short catheter / 3-way / silicone REF.: AB6R18, AB6R20, AB6R22, AB6R24 X-FLOW® Dufour Prostatectomy short catheter / 3-way / silicone	DHF Overview for Index of Silicone Prostatic Catheter (DMS document number VV-0105444) in DHF name BPH management / 1D2 -Prostatic catheters / Hydro X-Flow and X-Flow

REF.: AB6S18, AB6S20, AB6S22, AB6S24 **HYDRO X-FLOW®:** HYDRO X-FLOW® Couvelaire Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6118, XB6120, XB6122, XB6124 HYDRO X-FLOW® Delinotte Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6218, XB6220, XB6222, XB6224 HYDRO X-FLOW® Dufour Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6318, XB6320, XB6322, XB6324 **HYDRO X-FLOW® 80 ml:** HYDRO X-FLOW® Dufour Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6L18, XB6L20, XB6L22, XB6L24 HYDRO X-FLOW® Couvelaire Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6M18, XB6M20, XB6M22, XB6M24 HYDRO X-FLOW® Delinotte Prostatectomy catheter / 3-way / silicone / hydrogel coating REF.: XB6N18, XB6N20, XB6N22, XB6N24	

I. General Requirements

Methods of Conformity: recognised standard, other international standard, national standard, company standard, validated test etc

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: - Reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and - Consideration of the technical knowledge, experience and training and where applicable the medical and physical conditions of intended uses (design for lay, professional, disabled or other users).	A	**Quality Management:** **EN ISO 13485:2016** Medical devices – Quality management systems - Requirements for regulatory purposes **Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015*** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Design Verification:** **EN1616:1997/A1:1999:** Sterile urethral catheters for single use* **EN1618:1997:** Sterile Drainage Catheters and Accessory Devices for Single Use* **ASTM F623-89 :1999(2006):** Standard Performance Specification for Foley Catheter* *See annex A **Quality Procedures:** **SBA06022** Design Control **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA00076** Operations Control	PRESAFE certificates ISO13485 CMF Quality Manual CMF management reviews Device Master Record (DMR) *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Design Verification and Validation *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles,	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **-** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices	Risk Management Files Usability Assessment *In DMS see DHF overview* Design Verification and Validation

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: – Eliminate or reduce risks as far as possible (inherently safe design and construction), – Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, – Inform users of the residual risks due to any shortcomings of the protection measures adopted.		*see annex A **Design Verification:** **EN1616:1997/A1:1999:** Sterile urethral catheters for single use* **EN1618:1997:** Sterile Drainage Catheters and Accessory Devices for Single Use* **ASTM F623-89 :1999(2006):** Standard Performance Specification for Foley Catheter* *See annex A **Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedures:** **SBA06022** Design Control **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA60002** Labelling	*In DMS see DHF overview* Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	A	**Packaging*:** **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes *see annex A **Sterilization:** **ISO 11135:2014** Sterilization of health care products - Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices **ISO 11135/A1:2018*** AMENDMENT 1: Revision of Annex E, Single batch release	Design Verification and Validation *In DMS see DHF overview* Risk management Report *In DMS see DHF overview* Transportation Report and Rational *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* Clinical evaluation report

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		*see annex A **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 **Transport:** **ASTM D4169-16** Standard Practice for Performance Testing of Shipping Containers and Systems **ASTM D4332-14:2014**, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing **ASTM D5276-19**, Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D642-15**, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads **ASTM D999-08 (2015)** Standard Methods for Vibration Testing of Shipping Containers – Method A1 **ASTM D4728-17,** Standard Test Method for Random Vibration Testing of Shipping Containers – Method A **ASTM F2096-11,** Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) **ASTM F1929-15,** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration **ASTM F1886/F1886M-16** Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection *See annex A **Design Verification:** **EN1616:1997/A1:1999:** Sterile urethral catheters for single use* **EN1618:1997:** Sterile Drainage Catheters and Accessory Devices for Single Use*	*In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Certificate of supplier for conformity to ISO 11607 *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		ASTM F623-89 :1999(2006): Standard Performance Specification for Foley Catheter* *See annex A **Clinical:** **MEDDEV 2.7.1, Rev4** June 2016 Clinical evaluation: a guide for manufacturers and notified bodies **Quality Procedures:** **SBA06022** Design Control **SBA00087** Instruction for writing a clinical evaluation report **SBA00056** Stability and Transportation studies **SBA00076** Operations Control	
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to stresses which can occur during normal conditions of use.	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Design Verification:** **EN1616:1997/A1:1999:** Sterile urethral catheters for single use* **EN1618:1997:** Sterile Drainage Catheters and Accessory Devices for Single Use* **ASTM F623-89 :1999(2006):** Standard Performance Specification for Foley Catheter* *See annex A **Clinical:** **MEDDEV 2.7.1, Rev4** June 2016 Clinical evaluation: a guide for manufacturers and notified bodies **Quality Procedures:** **SBA06022** Design Control	Risk Management Files Usability Assessment *In DMS see DHF overview* Clinical evaluation report *In DMS see DHF overview* Design Verification and Validation *In DMS see DHF overview* Transportation Report and Rational *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		SBA00087 Instruction for writing a clinical evaluation report **SBA00056** Stability and Transportation studies **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions	
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Packaging*:** **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes *see annex A **Sterilisation:** **ISO 11135:2014** Sterilization of health care products - Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices **ISO 11135/A1:2018*** AMENDMENT 1: Revision of Annex E, Single batch release *see annex A **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 **Transport:** **ASTM D4169-16** Standard Practice for Performance Testing of Shipping Containers and Systems	Design Verification and Validation *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Transportation Report and Rational *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* Certificate of supplier for conformity to ISO 11607 *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		ASTM D4332-14:2014, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing **ASTM D5276-19**, Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D642-15**, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads **ASTM D999-08 (2015)** Standard Methods for Vibration Testing of Shipping Containers – Method A1 **ASTM D4728-17,** Standard Test Method for Random Vibration Testing of Shipping Containers – Method A **ASTM F2096-11,** Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) **ASTM F1929-15,** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration **ASTM F1886/F1886M-16** Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection *See annex A **Design Verification:** **EN1616:1997/A1:1999:** Sterile urethral catheters for single use* **EN1618:1997:** Sterile Drainage Catheters and Accessory Devices for Single Use* **ASTM F623-89 :1999(2006):** Standard Performance Specification for Foley Catheter* *See annex A **Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		EN 1041:2008 + A1: 2013 Information supplied by the manufacturer of medical devices **Quality Procedures:** **SBA06022** Design Control **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA00056** Stability and Transportation studies **SBA60002** Labelling	
6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended. 6.a Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Clinical:** **MEDDEV 2.7.1, Rev4** June 2016 Clinical evaluation: a guide for manufacturers and notified bodies **Biological Evaluation:** **EN ISO 10993-1:2009 / AC: 2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process **Quality Procedures:** **SBA00087** Instruction for writing a clinical evaluation report **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SUA06002** Biological Evaluation	Risk Management Files Usability Assessment *In DMS see DHF overview* Clinical evaluation report *In DMS see DHF overview* Biological Evaluation Report *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

II. Requirements regarding design and construction

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
7. Chemical, physical and biological properties			
7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must be paid to: – The choice of materials used, particularly as regards toxicity and, where appropriate, flammability – The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. – Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	A	**Quality Management:** **EN ISO 13485:2016** Medical devices – Quality management systems - Requirements for regulatory purposes **Biological Evaluation:** **EN ISO 10993-1:2009 / AC: 2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process **EU Regulation (EC) No 1907/2006** concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) **ASTM F1980-16** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device **Quality Procedures:** **SBA06022** Design Control **SUA06002** Biological Evaluation **SBA00076** Operations Control **SBA00056** Stability and Transportation studies	PRESAFE certificates ISO13485 CMF Quality Manual CMF management reviews Device Master Record (DMR) *In DMS see DHF overview* Design Verification and Validation *In DMS see DHF overview* Biological Evaluation Report *In DMS see DHF overview* Stability Report *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Biological Evaluation:**	Design Verification and Validation *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Biological Evaluation Report

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		EN ISO 10993-1:2009 / AC: 2010 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process **EN ISO 10993-7:2008 / AC: 2009** Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals **EU Regulation (EC) No 1907/2006** concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) **Quality Procedure:** **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA06022** Design Control **SUA06002** Biological Evaluation **SBA00076** Operations Control	*In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	A NA (Devices are not intended to administer medicinal products)	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Biological Evaluation:** **EN ISO 10993-1:2009 / AC: 2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process **Quality Procedures:** **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SUA06002** Biological Evaluation **SBA00076** Operations Control	Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Biological Evaluation Report *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
Section replaced by: 7.4. Where a device incorporates, as a integral part, a substance which, if used	NA		Devices do not contain any medicinal substances or human blood derivates

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex 1 of Directive 2001/83/EC. For the substance referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA), acting particularly through its committee in accordance with Regulation (EC) No 726/2004, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority of the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part a human blood derivative, the notified body shall, having verified the			

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
usefulness of the substance part of the medical device and talking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance is maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance in to the device as determined by the notified body, in order to ensure that the changes have no negative impact of the established benefit/risk profile of the addition of the substance in the medicinal device.			
Section 7.4 cont. When the relevant medicines competent authority (ie. the one involved in the initial	NA		Devices do not contain any medicinal substances or human blood derivates

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.			
7.5. The device must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulation and administrative provisions relating to the classification, packaging and labelling of dangerous substances. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as	A NA (Devices do not contain phthalates)	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Biological Evaluation:** **EN ISO 10993-1:2009 / AC: 2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process **Quality Procedures:** **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SUA06002** Biological Evaluation **SBA00076** Operations Control	Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Design Verification and Validation *In DMS see DHF overview* Biological Evaluation Report *In DMS see DHF overview* labelling *In DMS see DHF Overview* Clinical evaluation report *In DMS see DHF Overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I of Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing woman, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	NA (Devices do not contain phthalates)		
7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	**Risk Management:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices **Packaging*:** **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* Certificate of supplier for conformity to ISO 11607

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		*see annex A **Quality Procedures:** **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA00056** Stability and Transportation studies **SBA00076** Operations Control	*In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
8. Infection and microbial contamination			
8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	A	**Quality Management:** **EN ISO 13485: 2012 / AC: 2012**. Medical devices – Quality management systems – Requirements for regulatory purposes **Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Packaging*:** **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Design Verification and Validation *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* Clinical evaluation report *In DMS see DHF overview* IFU *In DMS see DHF overview* Certificate of supplier for conformity to ISO 11607 *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		*see annex A **Clean room and hygiene:** **EN ISO 14644-1:2015** Clean rooms and associated controlled environments. Part 1: Classification of air cleanliness **EN ISO 14644-4: 2001** Clean rooms and associated controlled environments. Part 4: Design, construction and start-up **EN ISO 14698-1:2003** Clean rooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods **EN ISO 11737-1:2018*** Sterilization of medical devices - Microbiological methods. Part 1: Determination of a population of microorganisms on products *see annex A **Sterilisation:** **ISO 11135:2014** Sterilization of health care products - Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices **ISO 11135/A1:2018*** AMENDMENT 1: Revision of Annex E, Single batch release *see annex A **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 **Clinical:** **MEDDEV 2.7.1, Rev4** June 2016 Clinical evaluation: a guide for manufacturers and notified bodies **Quality Procedures:** **SBA06069** Control of Clean rooms and Sterilisation **SBA60002** Labelling	

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		SBA06023 Risk Management **SBA00080** Usability Engineering Instructions **SBA00087** Instruction for writing a clinical evaluation report	
8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	A (See Regulatory Assessment in Annex B) A (See Regulatory Assessment in Annex B) A (See Regulatory Assessment in Annex B)	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Application of usability engineering to medical devices *see annex A **EU Regulation (EC) No 722/2012** concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin – Annex I, section 3 **EN ISO 22442-1: 2015** Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management **MEDDEV 2.4/1 Rev. 9 – June 2010** - MEDICAL DEVICES: Guidance document - Classification of medical devices – Section 4.2 Rule 17 **Quality Procedures:** **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA00076** Operations Control	Risk Management Files Usability Assessment *In DMS see DHF Overview* Device Master Record (DMR) *In DMS see DHF Overview* Regulatory Assessment of medical devices utilizing animal tissues and their derivatives *(see Annex B)* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A	Design Verification and Validation *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Device Master Record (DMR)

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
protective packaging is damaged or opened.		**Packaging*:** **EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes *see annex A **Sterilisation:** **ISO 11135:2014** Sterilization of health care products - Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices **ISO 11135/A1:2018*** AMENDMENT 1: Revision of An-nex E, Single batch release *see annex A **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 **Transport:** **ASTM D4169-16** Standard Practice for Performance Testing of Shipping Containers and Systems **ASTM D4332-14:2014**, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing **ASTM D5276-19**, Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D642-15**, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads **ASTM D999-08 (2015)** Standard Methods for Vibration Testing of Shipping Containers – Method A1 **ASTM D4728-17,** Standard Test Method for Random Vibration Testing of Shipping Containers – Method A	*In DMS see DHF overview* Transportation Report and Rational *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* Certificate of supplier for conformity to ISO 11607 *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
		ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) **ASTM F1929-15,** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration **ASTM F1886/F1886M-16** Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection *See annex A **Quality Procedures:** **SBA06022** Design Control **SBA00056** Stability and Transportation studies **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions	
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	A	**Sterilisation:** **ISO 11135:2014** Sterilization of health care products - Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices **ISO 11135/A1:2018*** AMENDMENT 1: Revision of Annex E, Single batch release *see annex A **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 **Quality Procedure:** **SBA06097** Supplier control	Device Master Record (DMR) *In DMS see DHF overview* Sterilization Report and Rational *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA		Devices are sold sterile
8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness	NA		Devices are sold sterile

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.			
8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	NA		Devices are not sold in both sterile and non-sterile condition.
9. Construction and environmental properties			
9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices **EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedures:** **SBA06022** Design Control **SBA60002** Labelling **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions **SBA00056** Stability and Transportation studies	Design Verification and Validation *In DMS see DHF overview* Risk Management Files Usability Assessment *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	A	**Risk Management*:** **EN ISO 14971:2012** Medical devices **–** Application of risk management to medical devices	Design Verification and Validation *In DMS see DHF overview* Risk Management Files

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
– The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, – Risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, – The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, – Risks arising where maintenance or calibration is not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	NA (Devices are used in standard environmental conditions without magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration) A NA (Devices do not have measuring or control mechanism and accuracy functions)	**EN 62366-1:2015** Medical devices – Part 1: Application of usability engineering to medical devices *see annex A **Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedures**: **SBA00056** Stability and Transportation studies **SBA60002** Labelling **SBA06023** Risk Management **SBA00080** Usability Engineering Instructions	Usability Assessment *In DMS see DHF overview* Device Master Record (DMR) *In DMS see DHF overview* Stability Report *In DMS see DHF overview* Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	NA		Devices are not intended to be exposed to flammable substances or to substances which could cause combustion.
10. Devices with a measuring function			
10.1 Devices with a measuring function must be designed and manufactured in such a	NA		Devices do not have a measuring function.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.			
10.2 The measurement, monitoring and display scales must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	NA		Devices do not have a measuring function.
10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1) (1) OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/61**7**/EEC (OJ No L 357, 7. 12 1989, p. 28)	NA		Devices do not have a measuring function.
11. Protection against radiation			
11.1 *General* 11.1.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	NA		Devices are not electrical equipment.
11.2 *Intended radiation* 11.1.2 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be	NA		Devices are not electrical equipment.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.			
11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	NA		Devices are not electrical equipment.
11.3 *Unintended radiation* 11.3.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	NA		Devices are not electrical equipment.
11.4 *Instructions* 11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	NA		Devices are not electrical equipment.
11.5 *Ionizing radiation* 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured in such a way to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	NA		Devices are not electrical equipment.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriated image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	NA		Devices are not electrical equipment.
11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	NA		Devices are not electrical equipment.
12. Requirements for medical devices connected to or equipped with an energy source			
12.1 Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks. 12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	NA		Devices are not connected to or equipped with an energy source.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
12.2 Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	NA		Devices are not connected to or equipped with an energy source.
12.3 Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	NA		Devices are not connected to or equipped with an energy source.
12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	NA		Devices are not connected to or equipped with an energy source.
12.5 Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	NA		Devices are not connected to or equipped with an energy source.
12.6 *Protection against electrical risks* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electrical shocks during normal use and in single fault condition, provided the devices are installed correctly.	NA		Devices are not connected to or equipped with an energy source.
12.7 *Protection against mechanical and thermal risks* 12.7.1 Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical	NA		Devices are not connected to or equipped with an energy source.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
risks connected with, for example, resistance, stability and moving parts.			
12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	NA		Devices are not connected to or equipped with an energy source.
12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	NA		Devices are not connected to or equipped with an energy source.
12.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	NA		Devices are not connected to or equipped with an energy source.
12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	NA		Devices are not connected to or equipped with an energy source.

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
12.*8 Protection against the risk posed to the patient by energy supplies or substances* 12.8.1 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	NA		Devices are not connected to or equipped with an energy source.
12.8.2 Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate, which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	NA		Devices are not connected to or equipped with an energy source.
12.9. *The function of the controls and indicators must be clearly specified on the devices*. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	NA		Devices are not connected to or equipped with an energy source.
13. Information supplied by the manufacturer			
13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	A A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices	Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	A A	**Quality Procedure:** **SBA60002** Labelling	
13.2 Where appropriate this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedure:** **SBA60002** Labelling	Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
13.3 *The label* must bear the following particulars: (a) The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label,	A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices	Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community;		**Quality Procedure:** **SBA60002** Labelling	
(b) The details strictly necessary for the user to identify the device and the contents of the packaging especially for the users;	A		
(c) Where appropriate, the word “STERILE”;	A		
(d) Where appropriate, the batch code, preceded by the word “LOT” , or the serial number;	A		
(e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	A		
(f) Where appropriate, an indication that the device is for single use. A manufacturer’s indication of single use must be consistent across the Community;	A		
(g) If the device is custom-made, the words “custom-made device”;	NA (Devices are not custom-made)		
(h) If the device is intended for clinical investigations, the words “exclusively for clinical investigations”;	NA (Devices are not intended for clinical investigations)		
(i) Any special storage and/or handling conditions;	A		

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
(j) Any special operating instructions;	A		
(k) Any warnings and/or precautions to take;	A		
(l) Year of manufacture for active device other than those covered by (e). This indication may be included in the batch or serial number;	NA (Devices are not active devices)		
(m) Where applicable, method of sterilization;	A		
(n) In the case of a device within the meaning of Article 1 (4a), an indication that the device contains a human blood derivative.	NA (Devices do not contain a human blood derivative)		
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedure:** **SBA60002** Labelling	Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
13.5 Wherever reasonable and practicable, the device and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedure:** **SBA60002** Labelling	Labelling *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
13.6 Where appropriate, the instructions for use must contain the following particulars:	A	**Labelling:** **EN ISO 15223-1:2016** Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements **EN 1041:2008 + A1: 2013** Information supplied by the manufacturer of medical devices **Quality Procedure:** **SBA60002** Labelling	IFU *In DMS see DHF overview* **See Rationale for Amcor paper change impact on PDC to Design validation M2 - Ref SD4019 to SD4022 (VV-0237589)*
(a) The details referred to in Section 13.3, with the exception of (d) and (e);			
(b) The performances referred to in Section 3 and any undesirable side effects;	A		
(c) If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	A		
(d) All the information needed to verify whether the device is properly installed and can operate correctly and safely,	A		
plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	NA (Devices do not need maintenance and calibration)		
(e) Where appropriate, information to avoid certain risks in connection with implantation of the device;	NA (Devices are not implanted in the patient)		
(f) Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigation or treatment;	A		
(g) The necessary instructions in the event of damage to the sterile packaging	A		
and, where appropriate, details of appropriate methods of resterilization;	NA		
(h) If the device is reusable, information on the appropriate processes to allow reuse,	NA (Devices are single use)		

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.			
Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.	NA (Devices are supplied sterile)		
If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;	A		
(i) Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	A		
(j) In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	NA (Devices do not emit radiation)		
The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:			

Essential requirements of Medical Device Directive 2007/47/EC	A/NA	Methods of Conformity	Identity of Specific Documents
(k) Precautions to be taken in the event of changes in the performance of the device;	NA (Devices performances cannot change)		
(l) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.;	NA (Devices are not specifically exposed to reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge pressure or variations in pressure, acceleration, thermal ignition sources)		
(m) Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	NA (Devices do not administer medicinal product)		
(n) Precautions to be taken against any special, unusual risks related to the disposal of the device;	NA (Devices do not have unusual risks related to the disposal)		
(o) Medicinal substances or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4:	NA (Devices do not contain medicinal substances or human blood derivative)		
(p) Degree of accuracy claimed for devices with a measuring function.	NA (Devices do not have measuring function)		
(q) Date of issue of the latest revision of the instructions for use	A		

Change log

Date	Init.	Short description of and reason for change
02/2010	FRSBU	Document created. CC SFOT-824LVB, MDD 2007/47/EC implementation
07/2014	FRSBU	Merging of Answer to Essential requirements for: • 80ml Hydro X Flow • Hydro X Flow • X Flow And answer to essential requirements for new Devices Dufour Short Tip - TW: 88671
04/2020	FRWMA	Updated document based on the 'Template Essential Requirements Check-list' – Version 7.0. Update of standard date following CC TW462941 New Amcor paper SD4022 for Multivac 2 at Tatabanya plant Discontinuation of (See CC TW 529339): • X-FLOW® Prostatectomy catheter straight tip 2-way 30-50 ml silicone (REF.: AB6618, AB6620, AB6622, AB6624) • X-FLOW® Prostatectomy catheter Delinotte tip 2-way 30-50 ml silicone (REF.: AB6718, AB6720, AB6722, AB6724)

Annex A - Rationale for use of standards for demonstration of conformity

Products concerned:

SILICONE PROSTATIC CATHETER

X-FLOW®:

X-FLOW® Prostatectomy catheter straight tip 3-way 30-50 ml silicone (REF.: AB6018, AB6020, AB6022, AB6024)
X-FLOW® Prostatectomy catheter Couvelaire tip 3-way 30-50 ml silicone (REF.: AB6118, AB6120, AB6122, AB6124)
X-FLOW® Prostatectomy catheter Delinotte tip 3-way 30-50 ml silicone (REF.: AB6218, AB6220, AB6222, AB6224)
X-FLOW® Prostatectomy catheter Dufour tip 3-way 30-50 ml silicone (REF.: AB6318, AB6320, AB6322, AB6324)
X-FLOW® Prostatectomy catheter Dufour tip 2-way 30-50 ml silicone (REF.: AB6418, AB6420, AB6422, AB6424)
X-FLOW® Prostatectomy catheter Couvelaire tip 2-way 30-50 ml silicone (REF.: AB6518, AB6520, AB6522, AB6524)
X-FLOW® Prostatectomy catheter Dufour tip 3-way 15-30 ml silicone (REF.: AB6A18, AB6A20, AB6A22, AB6A24)
X-FLOW® Prostatectomy catheter Couvelaire tip 3-way 15-30 ml silicone (REF.: AB6B18, AB6B20, AB6B22, AB6B24)
X-FLOW® Prostatectomy catheter straight tip 3-way 15-30 ml silicone (REF.: AB6C18, AB6C20, AB6C22, AB6C24)
X-FLOW® Prostatectomy catheter Delinotte tip 3-way 15-30 ml silicone (REF.: AB6E18, AB6E20, AB6E22, AB6E24)
X-FLOW® Prostatectomy short catheter over the guide 3-way 30-50 ml silicone (REF.: AB6G18, AB6G20, AB6G22, AB6G24)
X-FLOW® Prostatectomy short catheter straight tip 3-way 30-50 ml silicone (REF.: AB6H18, AB6H20, AB6H22, AB6H24)
X-FLOW® Prostatectomy short catheter straight tip 3-way 15-30 ml silicone (REF.: AB6J18, AB6J20, AB6J22, AB6J24)
X-FLOW® Prostatectomy short catheter Dufour tip 3-way 30-50 ml silicone (REF.: AB6R18, AB6R20, AB6R22, AB6R24)
X-FLOW® Prostatectomy short catheter Dufour tip 3-way 30-50 ml silicone (REF.: AB6S18, AB6S20, AB6S22, AB6S24)

HYDRO X-FLOW®:

HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Couvelaire tip 3-way 30-50 ml (REF.: XB6118, XB6120, XB6122, XB6124)
HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Delinotte tip 3-way 30-50 ml (REF.: XB6218, XB6220, XB6222, XB6224)
HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Dufour tip 3-way 30-50 ml (REF.: XB6318, XB6320, XB6322, XB6324)

HYDRO X-FLOW® 80 ml:

HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Dufour tip 3-way 50-80 ml (REF.: XB6L18, XB6L20, XB6L22, XB6L24)
HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Couvelaire tip 3-way 50-80 ml (REF.: XB6M18, XB6M20, XB6M22, XB6M24)
HYDRO X-FLOW® Post-operative catheter silicone with hydrogel coating Delinotte tip 3-way 50-80 ml (REF.: XB6N18, XB6N20, XB6N22, XB6N24)

The standards listed in the below table 1 have been used to assess conformity of certain performances according to the methods listed in the “Applicable part” column.

Table 1. Standards used for demonstration of conformity

Product	Standard	Applicable part	Rationale	Verification results
All codes	EN1616:1997 Sterile urethral catheters for single use & EN1618:1997 – Catheters other than intravascular catheters – Test methods for common properties	§4.4 & Annex A – Test method for determination of catheter strength resistance	Test method chosen to verify catheter strength performance	Conform
All codes		§4.5 & Annex B – Test method for determination of drainage funnel security connexion	Test method chosen to verify catheter connection to urine bag performance	Conform
All codes		§4.6 & Annex C – Test method for determination of balloon security	Test method chosen to verify catheter balloon resistance and no leakage under strength	Conform
All codes		§4.6 & Annex D – Test method for determination of inflation lumen leakage	Test method chosen to verify catheter balloon volume conservation	Conform
All codes		§4.8 & Annex E – Test method for determination of the flow rate in the catheter	Test method chosen to verify flow rate performance	Conform
All codes	EN1618:1997 – Catheters other than intravascular catheters – Test methods for common properties	Annex B – Test method for determining tensile properties	Test method chosen to verify tube/funnel assembling resistance	Conform
All codes			Test method chosen to verify valve/funnel resistance	Conform
All codes			Test method chosen to verify Balloon integrity	Conform
XB6L, XB6M, XB6N			Test method chosen to verify shape of the balloon after deflation	Conform
All codes	**ASTM D4169-16** Standard Practice for Performance Testing of Shipping Containers and Systems **ASTM F1980-16** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	all	See “QA evaluation of ASTM F1980-16 + D4169-16 + D5276-98(2017) + D4728-17” (DMS n°: VV-0219672) See “QA evaluation of ASTM D5276-19 (DMS N° VV-0291493) See “QA evaluation of ASTM D642-15	Conform

	ASTM D4728-17 Standard Test Method for Random Vibration Testing of Shipping Containers – Method A **ASTM D5276-19**, Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D642-15**, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads **ASTM F1929-15,** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		(DMS N° VV-0291000) See "QA evaluation of ASTM F1929-15 (DMS N° VV-0290995)	
All codes	**EN ISO 11607-1:2017** Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2017** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	all	See "QA evaluation of ISO11607-1+2 rev2017" (DMS n°: VV-0215373)	Conform
All codes	**ISO 11135/A1:2018** Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.	all	QA evaluation (DMS n°: VV-0258779)	Conform

	Amendment 1: Revision of Annex E, single batch release			
All codes	**EN 62366-1:2015** Medical devices — Application of usability engineering to medical devices.	all	Statement EN 62366-1-2015 (DMS n°: VV-0215849)	Conform
All codes	**EN ISO 11737-1: 2018** Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	all	See “QA evaluation of ISO11607-1+2 rev2017” (DMS n°: VV-0215373)	Conform
All product codes	**EN ISO 14971: 2012** Medical devices – Application of risk management to medical devices	all	Product Risk Assessment for Silicone Prostatic Catheters (DMS N°: VV-0217464)	Conform

Annex B: Regulatory Assessment of medical devices utilizing animal tissues and their derivatives

1. Background

An information has been received from the supplier concerning the presence of animal originated derivate in the current raw material of foils SC1163, SC1164 and SC1165 used on Multivac 2 (packaging machine) to package products [1].

Impacted references are:
REF.: AB6018, AB6020, AB6022, AB6024, AB6118, AB6120, AB6122, AB6124, AB6218, AB6220, AB6222, AB6224, AB6318, AB6320, AB6322, AB6324, AB6418, AB6420, AB6422, AB6424, AB6518, AB6520, AB6522, AB6524, AB6A18, AB6A20, AB6A22, AB6A24, AB6B18, AB6B20, AB6B22, AB6B24, AB6C18, AB6C20, AB6C22, AB6C24, AB6E18, AB6E20, AB6E22, AB6E24, AB6G18, AB6G20, AB6G22, AB6G24, AB6H18, AB6H20, AB6H22, AB6H24, AB6J18, AB6J20, AB6J22, AB6J24, AB6R18, AB6R20, AB6R22, AB6R24, AB6S18, AB6S20, AB6S22, AB6S24, XB6118, XB6120, XB6122, XB6124, XB6218, XB6220, XB6222, XB6224, XB6318, XB6320, XB6322, XB6324, XB6L18, XB6L20, XB6L22, XB6L24, XB6M18, XB6M20, XB6M22, XB6M24, XB6N18, XB6N20, XB6N22 and XB6N24.

An information has been received from the supplier concerning the presence of animal originated derivate in the current raw material manufacturing process used for the Halkey Roberts Valve V24500 [9].

Impacted references are:
REF.: AB6018, AB6020, AB6022, AB6024, AB6118, AB6120, AB6122, AB6124, AB6218, AB6220, AB6222, AB6224, AB6318, AB6320, AB6322, AB6324, AB6418, AB6420, AB6422, AB6424, AB6518, AB6520, B6522, AB6524, AB6A18, AB6A20, AB6A22, AB6A24, AB6B18, AB6B20, AB6B22, AB6B24, AB6C18, AB6C20, AB6C22, AB6C24, AB6E18, AB6E20, AB6E22, AB6E24, AB6G18, AB6G20, AB6G22, AB6G24, AB6H18, AB6H20, AB6H22, AB6H24, AB6J18, AB6J20, AB6J22, AB6J24, AB6R18, AB6R20, AB6R22, AB6R24, AB6S18, AB6S20, AB6S22, AB6S24, XB6118, XB6120, XB6122, XB6124), XB6218, XB6220, XB6222, XB6224, XB6318, XB6320, XB6322, XB6324, XB6L18, XB6L20, XB6L22, XB6L24,XB6M18, XB6M20, XB6M22, XB6M24), XB6N18, XB6N20, XB6N22, XB6N24.

The objective of this assessment is to evaluate the impact of the use of animal originated derivate in primary packaging for X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter devices.

2. Applicable Regulation

The applicable regulations are:

- Medical device Directive 93/42/EEC amended by Directive 2007/47/EC [2]
- Regulation (EU) No 722/2012 [3]
- EN ISO 22442-1 [4]

3. Supplier data and analysis

An investigation has been performed concerning X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter components containing animal originated derivatives is presented in table 1:

Table 1 *Supplier documentation and analysis regarding animal originated derivate on* X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter *device components*

Components		Patient / end user contact	Animal tissues and their derivatives?	Data	Analysis
First pouch	PET/PE peel and green tinted SC1163	Indirect contact	Yes, **tallow derivatives** could be used in Green foil	Based on supplier information, the production of these additives is subject to very severe processing that	The product is conform to the EMEA Note for Guidance 410/01 rev 3 [7]. This Note for

			282mm (*Polyester 12µm / polyethylene 40 µm peel green tinted*) [1]	meet or exceed the recommendations for complete inactivation of TSE agents. Products are in compliance with the EMEA/410/01 rev.3 [1]. The supplier – AMCOR – considers that the raw material does not pose any risk of transmitting animal spongiform encephalopathy agents via human medicinal products [1].	Guidance is applicable for human and veterinary medicinal products. The compliance with the EMEA Note for Guidance 410/01 rev 3 is sufficient to ensure compliance with the applicable requirements.
	Polypropylene / Ethylene Propylene Copolymer Blend / Polyethylene SC1164		Yes, **tallow derivatives** could be used in Transparent foil 302 mm *(Polyolefin EPN 60)*[1]		
Sterility-packaging (peel pouch)	Polypropylene / Ethylene Propylene Copolymer Blend / Polyethylene SC1165	No contact with the patient and no contact with user / surgeon (wearing gloves during surgery).	Yes, **tallow derivatives** could be used in Transparent foil 422 mm *(Polyolefin EPN 80)* [1]	Based on supplier information, the production of these additives is subject to very severe processing that meet or exceed the recommendations for complete inactivation of TSE agents. Products are in compliance with the EMEA/410/01 rev.3 [1]. The supplier – AMCOR – considers that the raw material does not pose any risk of transmitting animal spongiform encephalopathy agents via human medicinal products [1].	The product is conform to the EMEA Note for Guidance 410/01 rev 3 [7]. This Note for Guidance is applicable for human and veterinary medicinal products. The compliance with the EMEA Note for Guidance 410/01 rev 3 is sufficient to ensure compliance with the applicable requirements.
	60 g/m2 Medical Kraft Paper /10 g/m2 Grid Lacquer		No	The product shall contain no proteins, bovine or other animal or human chemicals [6]	This component does not incorporate and are not manufactured utilising tissues of animal origin. The Regulation 722/2012 is not applicable
Cycolac body of valve: ST2010, ST2013, ST2014, ST2015	Cycolac™ HMG47MD-1H1000 (ABS)	Indirect contact with the tissues of the patient.	Yes, **tallow derivatives** could be used in the manufacture of Cycolac body of valve and body's Carolina color [9] [11]	Based on supplier information, the tallow derived raw materials used fulfil requirements laid down in the Note for Guidance, EMEA/410/01 rev. 3 [9]	The products are in compliance with the EMEA Note for Guidance 410/01 rev 3 [7]. This Note for Guidance is applicable for human and veterinary medicinal products.
ST2010 body's Carolina color	Carolina Color 9C-302082-02				
ST2013 body's Carolina color	Carolina Color 9C-102012-02				
ST2014 body's Carolina color	Carolina Color 9C-201105-02				
ST2015 body's Carolina color	Carolina Color 9C-201105-02				

Based on previous data:

- All Animal tissues or derivatives used are tallow derivatives
- Assessments of the RMF have been done with conclusion concerning the acceptability of the risk [5].

4. Conformity assessment

Regulation 722/2012

The Regulation 722/2012 [3] shall not apply following Article 1 Section 4 (a), as, based on supplier data, animal tissues and their derivatives are tallow derivatives. These tallow derivatives submitted a process under conditions at least as vigorous as those laid down in Section 3 of Annex I of the Regulation 722/2012.

Standard EN ISO 22442-1

Based on supplier data, according to the Annex C5 of EN ISO 22442-1 [4], considering the manufacturing process conditions, the materials shall be considered as presenting an acceptable TSE risk, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived.

EMEA Note for Guidance 410/01 rev 3

This Note for Guidance 410/01 rev 3 [7] is applicable for human and veterinary medicinal products. Based on the fact that:

- The parts of the device which is conform to note for guidance, have no direct contact with the patient
- The medicinal products are designed to be ingested and metabolized by human

The compliance with the EMEA Note for Guidance 410/01 rev 3 is sufficient to ensure compliance with the applicable requirements for device which has no direct contact with patient.

Furthermore, based on supplier data, tallow derivatives are used. According to the Note for Guidance, tallow derivatives manufactured from tallow by rigorous processes are thought unlikely to be infectious and be considered in compliance for this Note for Guidance. The rigorous processes mentioned in the Note for Guidance are the same as those mentioned in Section 3 of Annex I of the Regulation 722/2012 [3] and Annex C5 of EN ISO 22442-1 [4].

Essential requirements – Annex I of Medical Device Directive 93/42/EEC amended by 2007/47/EC

The used of substances of animal origin in the manufacturing process has an impact on the Annex I, point 8.2 Essential requirements of Medical Device Directive 93/42/EEC amended by 2007/47/EC:

Essential requirements 8.2 of Medical Device Directive 2007/47/EC	A / NA	Justification
Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.	NA	Based on supplier data, the device is in conformity with Annex C5 of EN ISO 22442-1 [4], “Tallow derivatives, such as glycerol and fatty acids, manufactured from tallow by rigorous processes, are thought unlikely to be infectious. For this reason, such materials manufactured under the conditions at least as rigorous as those given below shall be considered as presenting an acceptable TSE risk, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived.” Based on supplier data, the Regulation 722/2012 [3] shall not apply following Article 1 Section 4 (a).
Notified bodies shall retain information on the geographical origin of the animals.	NA	See justification above
Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible	A	See Essential requirement 8.2

agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.		

EC Declaration of Conformity – Annex II Section 3.2 (c) of Medical Device Directive 93/42/EEC amended by 2007/47/EC

Based on previous data, the regulation 722/2012 [3] shall not apply based on Article 1 Section 4 (a). Consequently, the Section 3.2 c) of Annex II of Medical Device Directive 2007/47/EC concerning a statement indicating whether or not the device is manufactured utilizing tissues of animal origin is not applicable.

Classification criteria – Annex IX Section III of Medical Device Directive 93/42/EEC amended by 2007/47/EC

The classification of X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter was established taking into consideration its intended use.

The Rule 17 specifies "All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only"

However, based on the MEDDEV 2.4/1 [8], "The manufacture of some devices may use industrial raw materials which contain small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply." The rule 17 is not applicable for X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter devices.

Since it is an invasive device:

- for short term use, X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter are usually maintained in place no more than 7 days inserted through body orifice.

- not falling in any of the exceptions described on the applicable rule of the Annex IX, Medical Device Directive 93/42/EEC amended by 2007/47/EC

the device is classified as Class IIa Rule 5.

5. Conclusion

Based on the fact:

- All Animal tissues or derivatives used are tallow derivatives
- The Regulation 722/2012 shall not apply.
- The materials shall be considered as presenting an acceptable TSE risk, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived, according to the Annex C5 of EN ISO 22442-1
- The assessment of the RMF has been done and conclude that the risk is acceptable

It is assessed that the available data are sufficient to answer at the requirements of Medical Device Directive 93/42/EEC amended by 2007/47/EC. The use of tallow derivatives has no impact on X-FLOW® and HYDRO X-FLOW® Silicone Prostatic Catheter device classification.

6. References

[1] Document transmitted by AMCOR concerning the foil SC1163, SC1164 & SC1165:

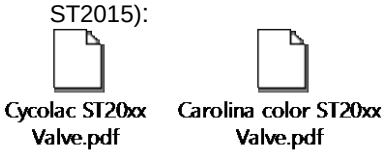
SC1164 & SC1165.pdf

SC1163.pdf

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended by Directive 2007/47/EC

[3] Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin.
[4] EN ISO 22442-1: 2015: Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
[5] Risk Assessment of medical devices utilizing animal tissues derivatives (VV-0265474)
[6] Request on material composition – AMCOR paper SD4022 (VV-0239445)
[7] Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 rev.3) – Notices from European Union Institutions, Bodies, Offices and Agencies.
[8] MEDDEV 2.4/1 Rev. 9 – June 2010 - MEDICAL DEVICES: Guidance document - Classification of medical devices.

[9] Document transmitted by SABIC concerning the Halkey Roberts Valve V24500 (ST2010, ST2013, ST2014, ST2015):



[10] Risk Assessment of medical devices utilizing animal tissues derivatives (VV-0265475)

[11] Request on material composition –Halkey Roberts Corporation ST2010 (VV-0236001), ST2013 (VV-0236004), ST2014 (VV-0236006), ST2015 (VV-0236005).

Signature Page for VV-0053983 v3.0

Approved	FRSAR Sebastien Arlie Product Improvement Specialist Technical / Specialist 16-Apr-2020 16:03:40 GMT+0000

Approved	FRSDR Sihem Darraji Senior Director, Regulatory Affairs - Interventional Urology Regulatory 19-Apr-2020 13:40:15 GMT+0000

Signature Page for VV-0053983 v3.0
Document Owner: FRALL Alexandra Limeul