APPLIED STANDARDS LISTING:

FOR MEDICAL DEVICE / DEVICE FAMILY:	**CAMSTENT COATED FOLEY CATHETER**
ASSOCIATED MODELS	***THE ASSOCIATED MODEL CODES IN THIS DEVICE FAMILY ARE THOSE AS LISTED IN THE APPLICABLE 'TECHNICAL FILE PART A - COVER DOCUMENT' AND 'EU DECLARATION OF CONFORMITY'***

APPLIED STANDARDS:

For the purposes of clarity, this documents under its title "Applied Standards" gives consideration to the following nature of documents, as listed below, in relation to their application in demonstrating aspects of conformity to requirements of EU Regulation 2017/745.

- "Harmonised Standards" as published in the current Official Journal of the European Union (OJEU) in relation to Medical Devices and EU Regulation 2017/745.
- "Common Specifications" adopted by implementing act in relation to Medical Devices and EU Regulation 2017/745.
- "Other standards and guidance's" may be applied to demonstrate the 'State Of the Art' where there is absence or deficiency in either a "Harmonised standard" or "Common Specification". *When electing to use 'other standards and guidance', justification for application shall be demonstrated.*

Applied Standard	**Description**	**Applied in Full or Part**	**Standard Status**			**Justification if standard is applied in part, and/or, if a standard or guidance is used that is not harmonised or a CS.**
			Harmonised Standard	**Common Specification**	**Other Standard or Guidance**	
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 14971:2019	Application of Risk management to medical devices.	Applied in Full	☐	☐	☒	This standard (2012 rev) was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 62366-1:2015 +A1:2020	Medical devices. Application of usability engineering to medical devices	Applied in Part	☐	☐	☒	Usability by UOUP method has only been applied as the OEM catheter design activity predates the standard, and was not applied at time of design. This standard (2008 Rev) was harmonised under the MDD 93/42/EEC, and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
MEDDEV 2.7/1 Rev. 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42 EEC and 90/385/EEC	Applied in Full	☐	☐	☒	To supplement details contained in the Regulation (EU) 2017/745 annex XIV in relation to requirements for Clinical Evaluation MEDDEV 2.7/1 Rev. 4 continues to offer the most up to date state of the art guidance in the absence of a Harmonised standard or CS.
EN ISO 80000-1:2013	Quantities and units. General	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
BS ISO 21501-4:2018	Determination of Particle size distribution	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 14644-2: 2015	Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	Applied in Part	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.

EN ISO 14644-3:2019	Cleanrooms and associated controlled environments. Test methods	Applied in Part	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments. Operations	Applied in Part	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Applied in Full	☐	☐	☒	This standard (2009 Rev) was harmonised under the MDD 93/42/EEC and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	Applied in Full	☐	☐	☒	This standard (2006 Rev) was harmonised under the MDD 93/42/EEC and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance and is referenced as a suitable guide in standard ISO 11607-1.
EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance and is referenced as a method in standard ISO 11607-1.
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance and is referenced as a method in standard ISO 11607-1.
EN 556-1:2001	Requirements for Medical Devices to be Designated STERILE. Part 1: Requirements for terminally sterilised medical devices	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 11737-1:2018	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products	Applied in Full	☐	☐	☒	This standard (2006/AC:2009 Rev) was harmonised under the MDD 93/42/EEC and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
EN ISO 11737-2:2020	Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation, and maintenance of a sterilization process	Applied in Full	☐	☐	☒	This standard (2009 Rev) was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 11137-1:2015 + A2:2019	Sterilisation of health care products. Radiation. Requirements for development, validation, and routine control of a sterilisation process for medical devices	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 11137-2:2015	Sterilisation of health care products -- Radiation -- Part 2: Establishing the sterilisation dose	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.

ISO 10993-1:2020	Biological Evaluation of Medical Devices – Evaluation and Testing within a risk management process	Applied in Full	☐	☐	☒	This standard (2009 Rev) was harmonised under the MDD 93/42/EEC, and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
EN ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal Welfare requirements.	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 10993-5:2009	Biological Evaluation of Medical Devices - Tests for in-vitro Cytotoxicity	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 10993-10: 2013	Biological evaluation of medical devices. Tests for irritation and skin sensitisation	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.
EN ISO 10993-12: 2012	Biological evaluation of medical devices. Sample preparation and reference materials	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 10993-16 :2017	Biological Evaluation of Medical Devices – Toxicokinetic study design for degradation products and leachables	Applied in Full	☐	☐	☒	This standard (2010 Rev) was harmonised under the MDD 93/42/EEC, and this latest Rev remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745
EN ISO 10993-17:2009	Biological Evaluation of Medical Devices – Establishment of Allowable Limits for Leachable Substances.	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 10993-18:2020	Biological Evaluation of Medical Devices – Chemical characterisation of materials	Applied in Full	☐	☐	☒	This standard (2009 Rev) was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Applied in Full	☐	☐	☒	This standard was harmonised under the MDD 93/42/EEC and remains the most applicable in relation, whilst not harmonised, to the MDR 2017/745.
EN ISO 20696:2018	Sterile urethral catheters for single use	Applied in Full	☐	☐	☒	In the absence of Harmonised Standard or CS, this standard serves to offer state of the art guidance.