

## EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, Penumbra, Inc.

Manufacturer: Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502, USA  
SRN: US-MF-000008514

Authorized EC Representative: Penumbra Europe GmbH  
Am Borsigturm 44  
13507 Berlin, Germany  
SRN: DE-AR-000004997

Design: Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502, USA

Manufacturing Facility: Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502, USA  
  
Penumbra, Inc.  
630 Roseville Parkway  
Roseville, CA 95747, USA

Product Category: Catheter, Embolectomy  
Product Trade Name: INDIGO Aspiration System  
Product Identification: See enclosed Attachment 1

Risk Classification: INDIGO Aspiration System  
Class III, Rule 6, Bullet 1 based on EU MDR 2017-745 - Annex VIII [Classification Rules - Chapter III]

Intended Purpose: The INDIGO Aspiration System is designed to remove thrombus from the vasculature using mechanical aspiration.

Basic UDI-DI: INDIGO Aspiration System  
081454801INDIGOSYSTEMYF

Technical Standards/Specifications: See enclosed Attachment 2

Notified Body: BSI Group The Netherlands B.V.  
Say Building, John M. Keynesplein 9, 1066 EP  
Amsterdam, Netherlands  
SIN: 2797

Selected conformity assessment  
procedure:

EU MDR 2017-745 – Annex IX

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of the EU MDR 2017-745, as transposed into the national laws of the EU member states.

This declaration is supported by:

- EU Quality Management System Certificate: MDR 739816, expires on 29-NOV-2026
- Technical Documentation Assessment Certificate Number: MDR 739880, expires on 29-NOV-2026

Signature:

Print Name & Title:  \_\_\_\_\_  
Deanna Kimlinger, Senior Regulatory Affairs Specialist

Check here if signing on behalf of the PRRC

Place of Issue: Alameda, California, USA

Date of Issue:

28-JAN-2022  
*(DD-MMM-YYYY)*

## ATTACHMENT 1 TO THE EU DECLARATION OF CONFORMITY

### Product List: “INDIGO™ System” (Class III, Rule 6)

Catalog Number	Product Description	Variant Basic UDI-DI
<b>Aspiration Catheters</b>		
CAT3	Aspiration Catheter 3, Straight, 150cm	081454801INDCAT5M
CAT5L125	Aspiration Catheter 5, Straight, 125cm	
CAT5L127	Aspiration Catheter 5, Straight, 127cm	
CAT5	Aspiration Catheter 5, Straight, 132cm	
CAT5MP125	Aspiration Catheter 5, MP, 125cm	
CAT5MP127	Aspiration Catheter 5, MP, 127cm	
CAT6STR30	Aspiration Catheter 6, Straight, 30cm	
CAT6STR40	Aspiration Catheter 6, Straight, 40cm	
CAT6STR50	Aspiration Catheter 6, Straight, 50cm	
CAT6STR60	Aspiration Catheter 6, Straight, 60cm	
CAT6STR70	Aspiration Catheter 6, Straight, 70cm	
CAT6STR80	Aspiration Catheter 6, Straight, 80cm	
CAT6STR90	Aspiration Catheter 6, Straight, 90cm	
CAT6STR100	Aspiration Catheter 6, Straight, 100cm	
CAT6STR110	Aspiration Catheter 6, Straight, 110cm	
CAT6STR115	Aspiration Catheter 6, Straight, 115cm	
CAT6STR120	Aspiration Catheter 6, Straight, 120cm	
CAT6STR125	Aspiration Catheter 6, Straight, 125cm	
CAT6STR132	Aspiration Catheter 6, Straight, 132cm	
CAT6	Aspiration Catheter 6, Straight, 135cm	
CAT6MP30	Aspiration Catheter 6, MP, 30cm	
CAT6MP40	Aspiration Catheter 6, MP, 40cm	
CAT6MP50	Aspiration Catheter 6, MP, 50cm	
CAT6MP60	Aspiration Catheter 6, MP, 60cm	
CAT6MP70	Aspiration Catheter 6, MP, 70cm	
CAT6MP80	Aspiration Catheter 6, MP, 80cm	
CAT6MP90	Aspiration Catheter 6, MP, 90cm	
CAT6MP100	Aspiration Catheter 6, MP, 100cm	
CAT6MP110	Aspiration Catheter 6, MP, 110cm	
CAT6MP115	Aspiration Catheter 6, MP, 115cm	
CAT6MP120	Aspiration Catheter 6, MP, 120cm	
CAT6MP125	Aspiration Catheter 6, MP, 125cm	
CAT6MP132	Aspiration Catheter 6, MP, 132cm	
CAT6MP135	Aspiration Catheter 6, MP, 135cm	
CAT8STR30	Aspiration Catheter 8, Straight, 30cm	
CAT8STR40	Aspiration Catheter 8, Straight, 40cm	
CAT8STR50	Aspiration Catheter 8, Straight, 50cm	
CAT8STR60	Aspiration Catheter 8, Straight, 60cm	
CAT8STR70	Aspiration Catheter 8, Straight, 70cm	
CAT8STR80	Aspiration Catheter 8, Straight, 80cm	

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Catalog Number	Product Description	Variant Basic UDI-DI	
CAT8STR85	Aspiration Catheter 8, Straight, 85cm		
CAT8STR90	Aspiration Catheter 8, Straight, 90cm		
CAT8STR95	Aspiration Catheter 8, Straight, 95cm		
CAT8STR100	Aspiration Catheter 8, Straight, 100cm		
CAT8STR110	Aspiration Catheter 8, Straight, 110cm		
CAT8STR115	Aspiration Catheter 8, Straight, 115cm		
CAT8TORQ30	Aspiration Catheter 8, TORQ, 30cm		
CAT8TORQ40	Aspiration Catheter 8, TORQ, 40cm		
CAT8TORQ50	Aspiration Catheter 8, TORQ, 50cm		
CAT8TORQ60	Aspiration Catheter 8, TORQ, 60cm		
CAT8TORQ70	Aspiration Catheter 8, TORQ, 70cm		
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm		
CAT8TORQ85	Aspiration Catheter 8, TORQ, 85cm		
CAT8TORQ95	Aspiration Catheter 8, TORQ, 95cm		
CAT8TORQ110	Aspiration Catheter 8, TORQ, 110cm		
CAT8XTORQ90	Aspiration Catheter 8, XTORQ, 90cm		
CAT8XTORQ100	Aspiration Catheter 8, XTORQ, 100cm		
CAT8XTORQ115	Aspiration Catheter 8, XTORQ, 115cm		
<b>Separators</b>			
SEP3	Separator 3, 190cm	081454801INDSEP89	
SEP5	Separator 5, 175cm		
SEP6	Separator 6, 175cm		
SEP7D	Separator 7D, 90cm		
SEP7130	Separator 7, 175cm		
SEP7	Separator 7, 190cm		
SEP8	Separator 8, 150cm		
SEPD	Separator D, 90cm		
SEP12	Separator 12, 150cm		
SEP1250	Separator 12, 90cm		
<b>Aspiration Catheter + Aspiration Tubing - KITS</b>			
CAT3KIT	Aspiration Catheter 3, Straight, 150cm - KIT		081454801INDKIT7M
CAT5L125KIT	Aspiration Catheter 5, Straight, 125cm - KIT		
CAT5L127KIT	Aspiration Catheter 5, Straight, 127cm - KIT		
CAT5KIT	Aspiration Catheter 5, Straight, 132cm - KIT		
CAT5MP125KIT	Aspiration Catheter 5, MP, 125cm - KIT		
CAT5MP127KIT	Aspiration Catheter 5, MP, 127cm - KIT		
CAT6STR30KIT	Aspiration Catheter 6, Straight, 30cm - KIT		
CAT6STR40KIT	Aspiration Catheter 6, Straight, 40cm - KIT		
CAT6STR50KIT	Aspiration Catheter 6, Straight, 50cm - KIT		
CAT6STR60KIT	Aspiration Catheter 6, Straight, 60cm - KIT		
CAT6STR70KIT	Aspiration Catheter 6, Straight, 70cm - KIT		
CAT6STR80KIT	Aspiration Catheter 6, Straight, 80cm - KIT		

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Catalog Number	Product Description	Variant Basic UDI-DI
CAT6STR90KIT	Aspiration Catheter 6, Straight, 90cm - KIT	
CAT6STR100KIT	Aspiration Catheter 6, Straight, 100cm - KIT	
CAT6STR110KIT	Aspiration Catheter 6, Straight, 110cm - KIT	
CAT6STR115KIT	Aspiration Catheter 6, Straight, 115cm - KIT	
CAT6STR120KIT	Aspiration Catheter 6, Straight, 120cm - KIT	
CAT6STR125KIT	Aspiration Catheter 6, Straight, 125cm - KIT	
CAT6STR132KIT	Aspiration Catheter 6, Straight, 132cm - KIT	
CAT6KIT	Aspiration Catheter 6, Straight, 135cm - KIT	
CAT6MP30KIT	Aspiration Catheter 6, MP, 30cm - KIT	
CAT6MP40KIT	Aspiration Catheter 6, MP, 40cm - KIT	
CAT6MP50KIT	Aspiration Catheter 6, MP, 50cm - KIT	
CAT6MP60KIT	Aspiration Catheter 6, MP, 60cm - KIT	
CAT6MP70KIT	Aspiration Catheter 6, MP, 70cm - KIT	
CAT6MP80KIT	Aspiration Catheter 6, MP, 80cm - KIT	
CAT6MP90KIT	Aspiration Catheter 6, MP, 90cm - KIT	
CAT6MP100KIT	Aspiration Catheter 6, MP, 100cm - KIT	
CAT6MP110KIT	Aspiration Catheter 6, MP, 110cm - KIT	
CAT6MP115KIT	Aspiration Catheter 6, MP, 115cm - KIT	
CAT6MP120KIT	Aspiration Catheter 6, MP, 120cm - KIT	
CAT6MP125KIT	Aspiration Catheter 6, MP, 125cm - KIT	
CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT	
CAT6MP135KIT	Aspiration Catheter 6, MP, 135cm - KIT	
CAT7STR50KIT	Aspiration Catheter 7, Straight, 50cm - KIT	
CAT7STR130KIT	Aspiration Catheter 7, Straight, 130cm - KIT	
CAT7STR160KIT	Aspiration Catheter 7, Straight, 160cm - KIT	
CAT7TORQ50KIT	Aspiration Catheter 7, TORQ, 50cm - KIT	
CAT7TORQ130KIT	Aspiration Catheter 7, TORQ, 130cm - KIT	
CAT7TORQ160KIT	Aspiration Catheter 7, TORQ, 160cm - KIT	
CAT7DKIT	Aspiration Catheter 7D, XTORQ, 50cm - KIT	
CAT7XTORQ130KIT	Aspiration Catheter 7, XTORQ, 130cm - KIT	
CAT7XTORQ160KIT	Aspiration Catheter 7, XTORQ, 160cm - KIT	
CAT8STR30KIT	Aspiration Catheter 8, Straight, 30cm - KIT	
CAT8STR40KIT	Aspiration Catheter 8, Straight, 40cm - KIT	
CAT8STR50KIT	Aspiration Catheter 8, Straight, 50cm - KIT	
CAT8STR60KIT	Aspiration Catheter 8, Straight, 60cm - KIT	
CAT8STR70KIT	Aspiration Catheter 8, Straight, 70cm - KIT	
CAT8STR80KIT	Aspiration Catheter 8, Straight, 80cm - KIT	
CAT8STR85KIT	Aspiration Catheter 8, Straight, 85cm - KIT	
CAT8STR90KIT	Aspiration Catheter 8, Straight, 90cm - KIT	
CAT8STR95KIT	Aspiration Catheter 8, Straight, 95cm - KIT	
CAT8STR100KIT	Aspiration Catheter 8, Straight, 100cm - KIT	
CAT8STR110KIT	Aspiration Catheter 8, Straight, 110cm - KIT	

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<b>Catalog Number</b>	<b>Product Description</b>	<b>Variant Basic UDI-DI</b>
CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT	
CAT8TORQ30KIT	Aspiration Catheter 8, TORQ, 30cm - KIT	
CAT8TORQ40KIT	Aspiration Catheter 8, TORQ, 40cm - KIT	
CAT8TORQ50KIT	Aspiration Catheter 8, TORQ, 50cm - KIT	
CAT8TORQ60KIT	Aspiration Catheter 8, TORQ, 60cm - KIT	
CAT8TORQ70KIT	Aspiration Catheter 8, TORQ, 70cm - KIT	
CAT8TORQ80KIT	Aspiration Catheter 8, TORQ, 80cm - KIT	
CAT8TORQ85KIT	Aspiration Catheter 8, TORQ, 85cm - KIT	
CAT8TORQ95KIT	Aspiration Catheter 8, TORQ, 95cm - KIT	
CAT8TORQ110KIT	Aspiration Catheter 8, TORQ, 110cm - KIT	
CAT8XTORQ90KIT	Aspiration Catheter 8, XTORQ, 90cm - KIT	
CAT8XTORQ100KIT	Aspiration Catheter 8, XTORQ, 100cm - KIT	
CAT8XTORQ115KIT	Aspiration Catheter 8, XTORQ, 115cm - KIT	
CATD30STR	Aspiration Catheter D, Straight, 30cm - KIT	
CATD35STR	Aspiration Catheter D, Straight, 35cm - KIT	
CATD40STR	Aspiration Catheter D, Straight, 40cm - KIT	
CATD45STR	Aspiration Catheter D, Straight, 45cm - KIT	
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT	
CATD30	Aspiration Catheter D, MP, 30cm - KIT	
CATD35	Aspiration Catheter D, MP, 35cm - KIT	
CATD40	Aspiration Catheter D, MP, 40cm - KIT	
CATD45	Aspiration Catheter D, MP, 45cm - KIT	
CATD	Aspiration Catheter D, MP, 50cm - KIT	
CAT12STR30KIT	Aspiration Catheter 12, Straight, 30cm - KIT	
CAT12STR40KIT	Aspiration Catheter 12, Straight, 40cm - KIT	
CAT12STR50KIT	Aspiration Catheter 12, Straight, 50cm - KIT	
CAT12STR60KIT	Aspiration Catheter 12, Straight, 60cm - KIT	
CAT12STR70KIT	Aspiration Catheter 12, Straight, 70cm - KIT	
CAT12STR80KIT	Aspiration Catheter 12, Straight, 80cm - KIT	
CAT12STR85KIT	Aspiration Catheter 12, Straight, 85cm - KIT	
CAT12STR90KIT	Aspiration Catheter 12, Straight, 90cm - KIT	
CAT12STR95KIT	Aspiration Catheter 12, Straight, 95cm - KIT	
CAT12STR100KIT	Aspiration Catheter 12, Straight, 100cm - KIT	
CAT12STR110KIT	Aspiration Catheter 12, Straight, 110cm - KIT	
CAT12STR115KIT	Aspiration Catheter 12, Straight, 115cm - KIT	
CAT12XTORQ30KIT	Aspiration Catheter 12, XTORQ, 30cm - KIT	
CAT12XTORQ40KIT	Aspiration Catheter 12, XTORQ, 40cm - KIT	
CAT12XTORQ50KIT	Aspiration Catheter 12, XTORQ, 50cm - KIT	
CAT12XTORQ60KIT	Aspiration Catheter 12, XTORQ, 60cm - KIT	
CAT12XTORQ70KIT	Aspiration Catheter 12, XTORQ, 70cm - KIT	
CAT12XTORQ80KIT	Aspiration Catheter 12, XTORQ, 80cm - KIT	
CAT12XTORQ85KIT	Aspiration Catheter 12, XTORQ, 85cm - KIT	

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<b>Catalog Number</b>	<b>Product Description</b>	<b>Variant Basic UDI-DI</b>	
CAT12XTORQ90KIT	Aspiration Catheter 12, XTORQ, 90cm - KIT		
CAT12XTORQ95KIT	Aspiration Catheter 12, XTORQ, 95cm - KIT		
CAT12XTORQ100KIT	Aspiration Catheter 12, XTORQ, 100cm - KIT		
CAT12XTORQ110KIT	Aspiration Catheter 12, XTORQ, 110cm - KIT		
CAT12XTORQ115KIT	Aspiration Catheter 12, XTORQ, 115cm - KIT		
CAT12HTORQ30KIT	Aspiration Catheter 12, HTORQ, 30cm - KIT		
CAT12HTORQ40KIT	Aspiration Catheter 12, HTORQ, 40cm - KIT		
CAT12HTORQ50KIT	Aspiration Catheter 12, HTORQ, 50cm - KIT		
CAT12HTORQ60KIT	Aspiration Catheter 12, HTORQ, 60cm - KIT		
CAT12HTORQ70KIT	Aspiration Catheter 12, HTORQ, 70cm - KIT		
CAT12HTORQ80KIT	Aspiration Catheter 12, HTORQ, 80cm - KIT		
CAT12HTORQ85KIT	Aspiration Catheter 12, HTORQ, 85cm - KIT		
CAT12HTORQ90KIT	Aspiration Catheter 12, HTORQ, 90cm - KIT		
CAT12HTORQ95KIT	Aspiration Catheter 12, HTORQ, 95cm - KIT		
CAT12HTORQ100KIT	Aspiration Catheter 12, HTORQ, 100cm - KIT		
CAT12HTORQ110KIT	Aspiration Catheter 12, HTORQ, 110cm - KIT		
CAT12HTORQ115KIT	Aspiration Catheter 12, HTORQ, 115cm - KIT		
<b>Aspiration Catheter + Lightning Aspiration Tubing - KITS</b>			
LITNG7XTORQ130	Lightning 7, XTORQ, 130cm - KIT		081454801INDLITNGSL
LITNG8STR85	Lightning 8, Straight, 85cm - KIT		
LITNG8TORQ85	Lightning 8, TORQ, 85cm - KIT		
LITNG8XTORQ115	Lightning 8, XTORQ, 115cm - KIT		
LITNG12XTORQ100	Lightning 12, XTORQ, 100cm - KIT		
LITNG12XTORQ115	Lightning 12, XTORQ, 115cm - KIT		
LITNG12HTORQ100	Lightning 12, HTORQ, 100cm - KIT		
LITNG12HTORQ115	Lightning 12, HTORQ, 115cm - KIT		

End of Product List

## ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

### Standards Listing

Note: As the EU MDR's Annex I, Item 1 (General Safety & Performance Requirements) requires 'state of the art,' Penumbra, Inc. follows the most current version of a standard, even if it has not been harmonized under the EU MDR 2017-745 based on gap analysis.

Standard	Title
<b>Quality System/Risk Management</b>	
BS EN ISO 13485:2016	Medical Devices – Quality management systems – requirement for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
<b>Biocompatibility</b>	
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
BS EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
BS EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
BS EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
BS EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
BS EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
BS EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
BS EN ISO 10993-18:2009	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
ISO/TR 10993-22:2017	Biological evaluation of medical devices - Part 22: Guidance on nanomaterials [Technical Report]
<b>Clinical</b>	
ISO 14155:2020***	Clinical investigation of medical devices for human subjects - Good clinical practice
<b>Performance Testing</b>	
BS EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications
BS EN 20594-1:1994/A1:1997 [= ISO 594-1:1986]	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements

## ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

Standard	Title
BS EN 62366-1:2015 +A1:2020*	Medical Devices – Application of Usability Engineering to Medical Devices
<b>Sterilization</b>	
BS EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 11135:2014+A1:2019	Sterilization of health-care products – Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11138-2:2017	Sterilization of health care products - Biological Indicators - Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes
BS EN ISO 11737-1:2018	Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products
BS EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
<b>Manufacturing/Packaging</b>	
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
BS EN ISO 11607-1:2020**** & BS EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems; Part 2: Validation requirements for forming, sealing and assembly processes
<b>Electrical Safety/EMC</b>	
IEC 60601-1: 2005/A1:2012, 3.1 edition (BS EN 60601-1: 2006/A12:2014)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC/BS EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6: :2010/A1:2013 [= BS EN 60601-1-6:2010/A1:2015]	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
BS EN ISO 10079-1:2015 +A1:2019	Medical Suction Equipment - Part 1: Electrically powered suction equipment
BS EN 62366-1 :2015 +A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
<b>Software</b>	
BS EN 62304 :2006+A1:2015	Medical device software - Software life-cycle processes
<b>Labeling</b>	
BS EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
BS 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 (ISO 15223-1:2016)
<b>Other applicable standards (USP, ANSI/AAMI, ASTM, etc.)</b>	

## ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

Standard	Title
USP <161>:2018	Medical Devices - Bacterial Endotoxin and Pyrogen Tests
USP <788>:2013	Particulate Matter in Injections
USP <85>:2018	Bacterial Endotoxins Test
ANSI/AAMI ST72:2019	Bacterial Endotoxins - Test methods, routine monitoring, and alternatives to batch testing
AAMI TIR42:2010	Evaluation of particulates associated with vascular medical devices
ASTM F1980:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169:2016**	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1929:2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096:2011	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
ASTM D6499:2018	Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products
ASTM F756:2017	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F640-2012	Standard Test Methods for Determining Radiopacity for Medical Use

\*All testing conducted and completed prior to March 2018 are fully in compliance with the IEC 62366 [EN 62366] version applicable at that time.

\*\* All testing conducted and completed prior to September 2016 are fully in compliance with the ASTM D4169-14 version applicable at that time.

\*\*\* All clinical investigations which were conducted and completed prior to 2021 are fully in compliance with the applicable EN ISO 14155 versions at that time.

\*\*\*\* All testing conducted and completed prior to February 2021 are fully in compliance with the BS EN ISO 11607-1 version applicable at that time.