

## DECLARATION OF CONFORMITY

**Manufacturer:** Interscope, Inc.  
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Northbridge, MA 01534  
USA

**European Representative:** EMERGO EUROPE  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

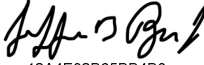
**Product:** EndoRotor<sup>®</sup> System, comprised of the following components:

- ESS-CONSOLE      EndoRotor<sup>®</sup> EndoSurgery System - Console
- 3.2-EPR-COL-OP      EndoRotor<sup>®</sup> 3.2 Endoscopic Powered Resection (EPR) Catheter – Colonoscope Long Olympus/Pentax
- 3.2-EPR-COL-O      EndoRotor<sup>®</sup> 3.2 Endoscopic Powered Resection (EPR) Catheter – Colonoscope Short Olympus
- 3.2-EPR-EGD-OP      EndoRotor<sup>®</sup> 3.2 Endoscopic Powered Resection (EPR) Catheter – Gastroscope Olympus/Pentax
- 3.2-EPR-EGD-F      EndoRotor<sup>®</sup> 3.2 Endoscopic Powered Resection (EPR) Catheter – Gastroscope Fuji
- 3.2-PED-COL-OP      EndoRotor<sup>®</sup> 3.2mm Powered Endoscopic Debridement (PED) Catheter – Colonoscope Long Olympus/Pentax
- 3.2-PED-EGD-F      EndoRotor<sup>®</sup> 3.2mm Powered Endoscopic Debridement (PED) Catheter – Gastroscope Fuji
- 3.2-PED-EGD-OP      EndoRotor<sup>®</sup> 3.2mm Powered Endoscopic Debridement (PED) Catheter – Gastroscope Olympus/Pentax
- 6.0-PED-EGD      EndoRotor<sup>®</sup> 6.0mm Powered Endoscopic Debridement (PED) Catheter
- 6.0-EPR-EGD      EndoRotor<sup>®</sup> 6.0mm Endoscopic Powered Resection (EPR) Catheter

<b>Classification (MDD):</b>	Class IIa under Rule 11 of Annex IX
<b>Conformity Assessment Route:</b>	CE Conformity Assessment Route according to Annex II, excluding Section 4, of Council Directive 93/42/EEC as amended by 2007/47/EC
<b>Product Accessories:</b>	<p>The following EndoRotor® System components are classified as accessories when provided as Standalone products:</p> <ul style="list-style-type: none"> <li>• 3.2-EPR-COL-OP EndoRotor® 3.2 Endoscopic Powered Resection (EPR) Catheter – Colonoscope Long Olympus/Pentax</li> <li>• 3.2-EPR-COL-O EndoRotor® 3.2 Endoscopic Powered Resection (EPR) Catheter – Colonoscope Short Olympus</li> <li>• 3.2-EPR-EGD-OP EndoRotor® 3.2 Endoscopic Powered Resection (EPR) Catheter – Gastroscope Olympus/Pentax</li> <li>• 3.2-EPR-EGD-F EndoRotor® 3.2 Endoscopic Powered Resection (EPR) Catheter – Gastroscope Fuji</li> <li>• 3.2-PED-COL-OP EndoRotor® 3.2mm Powered Endoscopic Debridement (PED) Catheter – Colonoscope Long Olympus/Pentax</li> <li>• 3.2-PED-EGD-F EndoRotor® 3.2mm Powered Endoscopic Debridement (PED) Catheter – Gastroscope Fuji</li> <li>• 3.2-PED-EGD-OP EndoRotor® 3.2mm Powered Endoscopic Debridement (PED) Catheter – Gastroscope Olympus/Pentax</li> <li>• 6.0-PED-EGD EndoRotor® 6.0mm Powered Endoscopic Debridement (PED) Catheter</li> <li>• 6.0-EPR-EGD EndoRotor® 6.0mm Endoscopic Powered Resection (EPR) Catheter</li> </ul>
<b>Classification (MDD):</b>	Class IIa under Rule 5 of Annex IX (EndoRotor Catheters) and
<b>Conformity Assessment Route:</b>	CE Conformity Assessment Route according to Annex II, excluding Section 4, of Council Directive 93/42/EEC as amended by 2007/47/EC (EndoRotor® Catheters)

We herewith declare that the above-mentioned devices comply with the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

**Notified Body:** BSI  
**Notified Body Identification No.:** 2797  
**EC Full Quality Assurance Certificate Number:** CE 613797  
**Date of First Issue:** 23 September 2015  
**Date of Declaration:** 25 May 2022

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**Signature:**

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**Jeffery B Ryan Jr**

**Position:**

Cofounder, President & CEO of Interscope, Inc.

The EndoRotor® System is designed and manufactured in compliance with the following standards:

Standard Reference	Standard Title
ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN 1618:1997 <sup>H</sup>	Catheters other than intravascular catheters. Test methods for common properties
EN ISO 10993-1:2018 <sup>H</sup>	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1: 2009/Cor1:2010)
EN ISO 10993-4: 2017 <sup>H</sup>	Biological Evaluation of Medical Devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
EN ISO 10993-5:2009 <sup>H</sup>	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-7:2008/Amd1:2019 <sup>H</sup>	Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
ISO 10993-10:2010	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2011 <sup>H</sup>	Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
EN ISO 11135-1:2014 <sup>H</sup>	Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
EN ISO 11607-1:2020 <sup>H</sup>	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2019 <sup>H</sup>	Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
ISO 17655-1:2006/(R)2013	Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness
ISO 14644-2:2015	Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-4:2001	Cleanrooms and associated controlled environments. Design, construction and start-up
ISO 14698-1:2003	Cleanrooms and associated environments. Biocontamination control. General principles and methods.
ISO 14698-2:2003	Cleanrooms and associated environments. Biocontamination control. Evaluation and interpretation of biocontamination data
EN ISO 14971:2019 <sup>H</sup>	Medical Devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
IEC 60601-1:2020 <sup>H</sup>	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010 + A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-18:2009	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62366:2015 (First edition) + A1:2014 <sup>H</sup>	Medical Devices – Application of usability engineering to medical devices

<sup>H</sup> Indicates Harmonized