| DECLARATION OF CONFORMITY | | Doc No.: | 10046 | |
|---|---|---|---|---|
| RETRACTION | REVEEL ENDOSCOPIC RETRACTOR | Doc Rev: | H | CN1059 |
| | | Page No.: | 1 / 3 | |

| Class of Medical Device: | |
|---|---|
| Product Codes: | RV093001<br>RT071401<br>RT072701<br>RT073001<br>RT081401<br>RT082701<br>RT083001 |
| Product Name: | REVEEL Endoscopic Retractor |
| Basic UDI-DI [GMN] | 489705430REVEELQC |
| Class: | Class IIa Medical Device |
| Rule: | RULE 7<br>[Medical Device Directive 93/42/EEC, as amended by directive 2007/47/EC ANNEX IX 2.3 Rule 7]<br>[Medical Device Regulation 2017/745 ANNEX VIII Chapter III, 5.3 Rule 7] |

| Manufacturer's Information: | |
|---|---|
| Manufacturer's Name: | RETRACTION Limited |
| Manufacturer's Address: | Room 1405, 135 Bonham Strand Trade Centre, 135 Bonham Strand, Sheung Wan, Hong Kong |

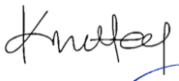
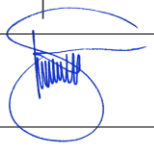
| Declaration: |
|---|
| It is hereby declared that the devices are listed in the Product Range section of this document conform to the provisions of the European Medical Device Directive 93/42/EEC, as amended by directive 2007/47/EC, and<br>European Medical Device Regulation (EU) 2017/745 |

| Supporting Documentation and Systems: | |
|---|---|
| Technical Documentation: | This declaration is supported by technical documentation as required by the Medical Device Regulation (Annex II) |
| Quality System: | This declaration is supported by a quality management system and technical documentation as required by the Medical Device Directive (Annex III) and Medical Device Regulation (Annex IX) which conforms to BS EN ISO 13485: 2016 |

| Notified Body: | |
|---|---|
| Name: | SGS BELGIUM NV |
| Notified Body Number: | CE 1639 |
| Certficate Number: | HK 20/42022 |
| Address: | SGS House, Noorderlaan 87, 2030 Antwerp, BELGIUM |

| European Authorized Representative: | |
|---|---|
| Name: | OBELIS S.A. |
| Contact: | +32 2 732 59 54 [Telephone]<br>www.obelis.net [E-mail] |
| Address: | Bd. Général Wahls 53, B-1030 Brussels, BELGIUM |

| Applicable Standards: | |
|---|---|
| MDR 2017/745 | Medical Device Regulation MDR 2017/745 |
| MDD 93/42/EEC | Medical Device Directive MDD 93/42/EEC |
| MEDDEV 2.12-1 | Guidelines on a medical devices vigilance system |
| MEDDEV 2.12-2 | Guidelines on post market clinical follow-up |
| MEDDEV 2.7.1 | Clinical Evaluation: A Guide for Manufacturers and Notified Bodies |
| ISO 13485 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| ISO 7153-1 | Surgical instruments - Materials – Part 1: Metals |
| BS EN ISO 13485 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| BS EN ISO 14971 | Medical devices – Application of risk management to medical devices |
| BS EN ISO 11607 – 1 | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| BS EN ISO 11607 – 2 | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes |
| BS EN ISO 10993 – 1 | Biological evaluation of medical devices – Part 1: Evaluation and testing |
| BS EN ISO 10993 – 5 | Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity |
| BS EN ISO 10993 – 10 | Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity |
| BS EN ISO 11137 – 1 | Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |
| BS EN ISO 11137 – 2 | Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose |
| BS EN ISO 14644 – 1 | Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration |
| BS EN 556-1 | Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices |
| BS EN ISO 15223-1 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements |
| BS EN 1041 | Information supplied by the manufacturer of medical devices |
| ASTM F1140 | Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages |
| ASTM F88 | Standard Test Methods for seal strength of flexible Barrier materials |
| ASTM F2096 | Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) |
| ASTM F1980 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |
| ASTM F1886 | Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection |
| ASTM D4169 | Standard Practice for Performance Testing of Shipping Containers and Systems |
| ASTM D4332 | Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing |
| ASTM D999 | Standard Test Methods for Vibration Testing of Shipping Containers |

| Approvals | Name | Signature | Date |
|---|---|---|---|
| Created by: | Kirsten Hill |  | 2023-09-06 |
| Approved by: | Stuart Moran |  | 2023-09-06 |