# SPECIFICATION

| DESCRIPTION | | | PAGES |
|---|---|---|---|
| Technical Product Data Sheet, MEDENA - Tubing (Sterile) | | | 1 (5) |
| DOC NO | ENCLOSURE | DATE | STATUS |
| SP-MH-0012-D | None | 2012-10-23 | Approved |
| PREPARED BY | ISSUED BY | APPROVED BY | |
| Gertzen, Christian | Gertzen, Christian | Walfridsson, Karin | |

# TECHNICAL PRODUCT DATA SHEET
# MEDENA Product range – Tubing (Sterile)

## Contents

# 1 SUPPLIER DETAILS

| | |
|---|---|
| **Manufacturer** | Wellspect HealthCare |
| **Address** | Aminogatan1, P.O. Box 14, 43121 Mölndal |
| **Country** | Sweden |
| **Website** | www.wellspect-healthcare.com |
| **Phone no.** | +46 31 376 40 00 |

# 2 PRODUCT RANGE

| REF | GTIN no.* | Description | No. of items |
|---|---|---|---|
| 68108 | | Medena Tubing 2m 5.5x8mm | |
| 68130 | | Medena Tubing 3.5m 5.5x8mm | |
| 68121 | | Medena Suction Set 2m 5.5x8mm | 2x50 |
| 68167 | | Medena Connection Set 2m 5.5x8mm | 2x50 |
| 68115 | | Medena Connection Set 3.5m 5.5x8mm | 2x35 |
| 68157 | | Medena Suction Tubing Set 1+2.5m | 2x20 |
| 68106 | | Medena Suction Set 2m 5.5x8mm | 2x50 |
| 68114 | | Medena Suction Set 3.5m 5.5x8mm | 2x35 |
| 68207 | | Medena Suction Set 2m 5.5x8mm | 2x50 |

* Wellspect HealthCare applies GS1 rules for barcoding of shelf- and transport box.

# 3 PRODUCT AND REGULATORY INFORMATION

| | |
|---|---|
| **Product trade mark or trade name** | Medena |
| **Description** | Used for removal of fluids in wound cavity during surgery |
| **Intended use of the product** | Medena assortment is a single use disposable system consisting of suction tips and tubing intended for removal of body fluids during surgery. |
| **Does the device need to be used in combination with other devices, adapters or other accessories?** | Yes, standard vacuum suction systems. |
| **Is the product a medical device?** | Yes |
| **Is the device an implant?** | No |
| **Are handling instructions included in the package?** | No |

| | |
|---|---|
| **Classification according to MDD 93/42/EEC?** | ☐ I<br>☐ I<br>☐ IIa, non-sterile<br>☒ IIa, sterile<br>☐ IIb<br>☐ III |
| **Classification rule?** | 6 and 11 |
| **Notified Body number** | 0086 |
| **CE certificate no.?** | CE 0086 |
| **Are handling instructions included in the package?** | No |
| **List of applicable international standards/vertical norms related to the product:** | MDD 93/42 EEC<br>EN 556 |

# 4 PRODUCT MATERIALS

| | |
|---|---|
| **Device material** | PVC, Medical grade |

# 5 PRODUCT COMPONENTS

| | |
|---|---|
| **DEHP, Di(2-ethylhexyl) phthalate?** | Yes, in soft tubing and cone to vacuum pump |
| **Natural rubber latex in device?** | No |
| **Liquids?** | No |
| **Power source?** | No |
| **Pharmaceuticals?** | No |
| **Animal source/origin** | No |
| **Contraceptives?** | No |
| **Does the device have a measuring function?** | No |

# 6 STERILIZATION

| | |
|---|---|
| **Method of sterilization:** | EtO |
| **Is the device compatible with the EtO sterilization?** | Yes |
| **Can the product be resterilized?** | Yes |
| **What method of re-sterilisation is the device validated for?** | EtO |
| **Has your product been evaluated for resterilization?** | Yes |
| **Limit for temperature during sterilization cycle** | < 55 ºC |
| **Limit for evacuation pressure during sterilization cycle** | 700 mbar |
| **How many times can the device be sterilized?** | 4 times |

| | |
|---|---|
| **Does the re-sterilization impact the shelf life or performance ?** | No |

# 7 PRODUCT CONTAMINATION CONTROL

| | |
|---|---|
| **Is the device manufactured in a controlled environment which complies with ISO 13485?** | Yes |
| **Is the device tested for bio burden?** | Yes |
| **Do the products require a non-pyrogenic claim?** | No |

# 8 HUMAN/ANIMAL ORIGIN

| | |
|---|---|
| **Does the product contain any materials of human origin?** | No |
| **Does the product contain any materials of animal origin?** | No |
| **Does the product come into contact with material of animal origin during the manufacturing process?** | No |

# 9 PACKAGING AND STORAGE

| | |
|---|---|
| **Mode of delivery** | Single item packages put in shelf boxes that are packaged into one transport box. |
| **Is the device available in bulk?** | Yes |
| **Is the device manufactured in a controlled environment which complies with ISO 13485?** | Yes |
| **Does the device need to remain in its primary packaging?** | No |
| **Is the product expiration dated?** | Yes |
| **Is the expiration date relative to the packaging and/or the product degradation?** | Packaging and product degradation. |
| **Shelf life** | 3 years |
| **Special storage conditions?** | Dry environment, room temperature. |

# 10 PACKAGING COMPONENTS

| | |
|---|---|
| **Single package** | Heat sealable breathable coated paper 99g/m², 100 µm multilayer polyelhylene/polyamide coextruded |
| **Shelf box** | Corrugated cardboard box |
| **Transport box** | Corrugated cardboard box |
| **Natural rubber latex in package?** | No |

# 11 ENVIRONMENTAL SECTION

| | |
|---|---|
| **Does the product or products packaging (ink, labels, banding, packing material etc.) contain heavy metals e.g. Pb, Hg, Cd, Dr in such a way that the combined totals exceed 100ppm?** | No |
| **Does the product contain, or is manufactured or sterilised with ozone depleting agents:**<br>- **CFC's (Freon, Halon, Carbon Tetrachloride, Methyl Chloroform)**<br>- **HCFC's** | No |
| **Chlorine bleached materials (product / packaging)** | No/No |
| **Recycled materials (product/packaging)** | No/Yes |
| **Does a recognised environmental label exist for the product area?** | No |
| **Does the product carry an environmental label?** | No |
| **Can the product and its packaging be recycled?** | See 12 |

# 12 WASTE HANDLING

Recommendations for waste handling:

| | **Incineration** | **Recycling** |
|---|---|---|
| **Product** | Yes | |
| **Item package** | Yes | |
| **Shelf box** | | Yes |
| **Transport box** | | Yes |

# 13 RECYCLING LABEL

| | |
|---|---|
| **Product** | No |
| **Item package** | No |
| **Carton (shelf box)** | Yes |
| **Shipping box** | Yes |