

Rev. 2018/12

To whom it may concern:

## **TECHNICAL DATA SHEET**

# **Henry Schein Sterireel sterilization rolls**

## **Product assortment:**

| REF     | Description                                 | Contents  |
|---------|---|-----------|
| 9002993 | HS-Sterireel sterilisation roll, 100mm      | 1 / 200 m |
| 9002989 | HS-Sterireel sterilisation roll, 100mm      | 1 / 100 m |
| 9002991 | HS-Sterireel sterilisation roll, 50mm       | 1 / 200 m |
| 9002987 | HS-Sterireel sterilisation roll, 50mm       | 1 / 100 m |
| 9002990 | HS-Sterireel sterilisation roll, 65 x 200mm | 1 / 100 m |
| 9002992 | HS-Sterireel sterilisation roll, 75mm       | 1 / 200 m |
| 9002988 | HS-Sterireel sterilisation roll, 75mm       | 1 / 100 m |
| 9880485 | HS-Sterireel sterilisation roll, 150mm      | 1 / 200 m |
| 9880486 | HS-Sterireel sterilisation roll, 200 mm     | 1 / 200 m |
| 9880487 | HS-Sterireel sterilisation roll, 250 mm     | 1 / 200 m |
| 9880488 | HS-Sterireel sterilisation roll, 300 mm     | 1 / 200 m |

## Intended use:

For use as packing material for medical devices in sterilization by steam, ethylene oxide gas in healthcare establishments.

# Sterilization method:

Compatible with Steam and Ethylene Oxide (EO) sterilization methods. The reels maintain sterility of the device for up to one year post sterilization under appropriate storage conditions. Recommended sealing temperature: 200°C±10°C, sealing time: 2.5 seconds.

## Sterilization parameters:

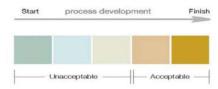
| Sterilization Cycle Parameter | Gravity / Steam |           | Ethylene Oxide Gas |
|-------------------------------|-----------------|-----------|--------------------|
| Time (min)                    | 30              | 4         | 100-120            |
| Temperature(°C)               | 121             | 134       | 50                 |
| Relative humidity(%)          | N/A             | N/A       | 60-85              |
| Sterilant Concentration       | N/A             | N/A       | 600                |
| Drying-Aeration time          | 15-30 min       | 20-30 min | 12 hrs             |

## **Process Indicator Color Change Guide:**

#### Steam Sterilization

# Start process development Finish Unacceptable Acceptable

#### **EO** Sterilization



### Material:

Pouches and corresponding packaging is latex-free. Non-tearing, thick multi-layer film made from a combination of polypropylene and polyethylene. High quality, porous 60 g/m2 medical grade paper.

## Regulatory:

In accordance with requirements of the MDD93/42/EEC. In conformity with the relevant harmonized standards EN 868-5, EN ISO 11607-1 and international Standard ISO 11140-1

## Shelf-life:

Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C. Shelf life of the product: 36 months. For single-use only.



Please do not hesitate to contact us if you have any questions or comments.



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