

## Sterile irrigation set HY-110005


### Technical data sheet - Medical Device

#### 1. Administrative information about the company

Date of issue : 01/10/2015

|     |  |  |
|-----|--|--|
| 1.1 | Name : Hygitech SAS  |  |
| 1.2 | Complete address :<br>25 rue Bleue<br>75009 PARIS – FRANCE | Phone: +33 1 48 01 32 89<br>Fax : +33 1 48 01 32 80<br>e-mail : info@hygitech.fr<br>Web site : www.hygitech.fr |
| 1.3 | Contact information Materiovigilance : Claudia Régnier     | Phone : +33 1 45 91 31 82<br>Fax : +33 1 48 65 67 23<br>e-mail : qualite@hygitech.fr                           |

#### 2. Information about the equipment

| 2.1       | <b>Trade name:</b> Sterile irrigation set  |                                |                               |        |                               |           |                 |                                |                   |
|-----------|--|--------------------------------|-------------------------------|--------|-------------------------------|-----------|-----------------|--------------------------------|-------------------|
| 2.2       | <b>Class of MD :</b> Class ISTERILE<br><b>European Directive:</b> 93/42/EEC including Directive 2007/47/CE<br><b>According Annex n° V</b><br><b>Notified body:</b> 0120 SGS UK LIMITED<br><b>Date of first launch on the UE market:</b> 2012_02<br><b>Manufacturer :</b> Hygitech  |                                |                               |        |                               |           |                 |                                |                   |
| 2.3       | <b>Product description :</b><br>With dental surgeons using two kinds of irrigation – external and internal, Hygitech offers irrigation kits that answer both needs, as well as 1-way and 2-ways systems.<br><br>It is essential that the silicone tubes are compatible with the implant motors. This is why we manufacture many irrigation sets models, to offer optimum compatibility.<br><br>Compatible with :<br><table><tr><td>W&amp;H</td><td>Elcomed</td></tr></table><br> | W&H                            | Elcomed                       |        |                               |           |                 |                                |                   |
| W&H       | Elcomed  |                                |                               |        |                               |           |                 |                                |                   |
| 2.4       | <b>Packaging :</b> <table><tr><th>Reference</th><th>OU<br/>Order unit</th><th>CARTON</th><th>MOQ<br/>Minimum order quantity</th></tr><tr><td>HY-110005</td><td>Box of 10 units</td><td>Carton of 10 boxes of 10 units</td><td>1 box of 10 units</td></tr></table><br><b>Labelling :</b> Unknown  | Reference                      | OU<br>Order unit              | CARTON | MOQ<br>Minimum order quantity | HY-110005 | Box of 10 units | Carton of 10 boxes of 10 units | 1 box of 10 units |
| Reference | OU<br>Order unit   | CARTON                         | MOQ<br>Minimum order quantity |        |                               |           |                 |                                |                   |
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|--|---|---|--|
| <b>2.8</b>                               | <b>Composition of the product, dimensions and accessories :</b>   |   |  |
|  | <b>Elements</b>   | <b>Material</b>                         | <b>Dimension</b>                       |
|  | Cap   | Polyethylene                            |  |
|  | Spike   | ABS                                     |  |
|  | Tube 1  | PVC                                     | OD=4,1mm ID=2,9 mm L=50 cm             |
|  | Roller clamp  | ABS                                     |  |
|  | Connector   | ABS                                     |  |
|  | Silicone tube 1   | Silicone                                | OD=4,9mm ID=3,1 mm L=19 cm             |
|  | Connector   | ABS                                     |  |
|  | Tube 2  | PVC                                     | OD=4,1mm ID=2,9 mm L=10 cm             |
|  | Connector   | ABS                                     |  |
|  | Silicone tube 2   | Silicone                                | OD=4,9mm ID=3,1 mm L=6,5 cm            |
|  | Connector   | ABS                                     |  |
|  | Tube 3  | PVC                                     | OD=4,1mm ID=2,9 mm L=22 cm             |
|  | 3-way stopcock  | Polycarbonate & Polyethylene            |  |
|  | <b>2 ways system</b>  |   |  |
|  | Luer lock Male  | ABS                                     | ID=2,5mm                               |
|  | Tube 1  | PVC                                     | OD=2,5mm ID=1,1 mm L=200 cm            |
|  | Connector Y   | PVC                                     | ID=2,5mm                               |
|  | Tube 2 (x2)   | PVC                                     | OD=2,5mm ID=1,1 mm L=15 cm             |
|  | <b>1 way system</b>   |   |  |
|  | Luer lock Male  | ABS                                     | ID=2,5mm                               |
|  | Tube 1  | PVC                                     | OD=2,5mm ID=1,1 mm L=200 cm            |
|  | <b>Accessories</b>  |   |  |
|  | N-shape hook (x5)   | Polyethylene                            |  |
|  | S-shape hook (x6)   | Polyethylene                            |  |
|  | <b>Presence of :</b>  |   |  |
|  | Latex   | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
|  | Phthalates (DEHP)   | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO            |
|  | Products of animal or biological origin   | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| <b>2.9</b>                               | <b>Field - Indications:</b> Unknown   |   |  |
| <b>3. Method of sterilizing</b>          |   |   |  |
|  | <b>Sterile :</b> YES<br><b>Sterilization method:</b> Ethylene Oxide (EO)  |   |  |
| <b>4. Storage conditions</b>             |   |   |  |
|  | <b>Normal conditions of storage:</b> Store in a dry environment. The product must be stored in a room with a humidity rate under 80% and equipped with a ventilating system<br><b>Special precautions:</b> Keep this product away from direct sunlight<br><b>Shelf life:</b> 3 years<br><b>Presence of temperature indicators:</b> NO |   |  |
| <b>5. Safety in use</b>                  |   |   |  |
| <b>5.1</b>                               | <b>Technical security:</b> N/A  |   |  |
| <b>5.2</b>                               | <b>Biosecurity:</b> N/A   |   |  |
| <b>6. Advices of use</b>                 |   |   |  |
|  | Refer to the manual for more information on the instructions for use, indications, precautions and contra-indications   |   |  |
| <b>7. Additional product information</b> |   |   |  |
|  | <b>Single use:</b> YES  |   |  |
| <b>8. Related documents</b>              |   |   |  |
|  | Unknown   |   |  |