

Haemostatic sponge

Technical data sheet - Medical Device

- 1. Administrative information about the company Date of issue : 16/05/2023

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| 1.1 | Name : Hygitech SAS |
| 1.2 | <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Complete address : 55 Avenue Foch - 75116 Paris </div> <div style="width: 50%;"> Phone: +33 1 48 01 32 89 e-mail : info@hygitech.fr Web site : www.hygitech.fr </div> </div> |
| 1.3 | <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Contact information Materiovigilance : Mathilde LEBON </div> <div style="width: 50%;"> Phone : +33 1 42 46 88 55 e-mail : qualite@hygitech.fr </div> </div> |

2. Information about the equipment

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| 2.1 | Trade name: Haemostatic sponge |
| 2.2 | Class of MD : Class III European Directive: 93/42/EEC including Directive 2007/47/CE According Annex n° II Notified body: DNVGL Nemko Date of first launch on the UE market: 01/2016 Manufacturer : HYGITECH |

2.3 Product description :

It can be used in various surgical procedures for haemostasis ; they are used when the control of bleeding (capillaries, veins and arterioles) by conventional procedures of pressure and ligation is ineffective.



Characteristics :

HYGITECH Haemostatic Sponge is made of high quality gelatine, highly

| | <p>processed and purified,</p> <ul style="list-style-type: none"> - Delivered in single sterile blister packs. - Unique format 1x1x1cm - Available in pack of 10 and 32 sterile blisters <p><u>Easy to use and malleable</u> The haemostatic sponge can be cut to fit the bleeding area.</p> <p><u>Insoluble in water</u> As a macro-porous sponge, it is insoluble in water with a rapid absorption capacity equivalent to 40 to 50 times its weight in blood or other liquids.</p> <p><u>Biocompatible and non-pyrogenic</u> It offers good adhesion to the bleeding site promoting the formation of the fibrin network which is essential to efficient coagulation.</p> <p><u>Resorption</u> Complete resorption in 3-4 weeks</p> | | | | | | | | | | | | | | | | | | |
|---|--|--|-------------------------------|------------|-------------------------------|-----------------------------|-----------------|---------------------------------|-------------------|----------|-----------------|---------------------------------|--|-------------------|------------------------------|--|---|---|-----------------------------|
| 2.4 | <p>Packaging :</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr style="background-color: #ff8c00; color: white;"> <th style="width: 25%;">Reference</th><th style="width: 25%;">OU Order unit</th><th style="width: 25%;">CARTON</th><th style="width: 25%;">MOQ Minimum order quantity</th></tr> <tr> <td>HY-80208</td><td>Box of 10 units</td><td>Carton of 195 boxes of 10 units</td><td>1 box of 10 units</td></tr> <tr> <td>HY-80210</td><td>Box of 32 units</td><td>Carton of 195 boxes of 32 units</td><td>1 box of 32 units</td></tr> </table> <p>Labelling : Unknown</p> | Reference | OU Order unit | CARTON | MOQ Minimum order quantity | HY-80208 | Box of 10 units | Carton of 195 boxes of 10 units | 1 box of 10 units | HY-80210 | Box of 32 units | Carton of 195 boxes of 32 units | 1 box of 32 units | | | | | | |
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| 2.8 | <p>Composition of the product, dimensions and accessories :</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr style="background-color: #ff8c00; color: white;"> <th style="width: 33%;">Elements</th><th style="width: 33%;">Material</th><th style="width: 33%;">Dimensions</th></tr> <tr> <td>Sponge</td><td>Gelatin from porcine origin</td><td>1x1x1cm</td></tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #ff8c00; color: white;"> <th colspan="3">Presence of :</th></tr> <tr> <td style="width: 60%;">Latex</td><td style="width: 20%; text-align: center;"><input type="checkbox"/> YES</td><td style="width: 20%; text-align: center;"><input checked="" type="checkbox"/> NO</td></tr> <tr> <td>Phthalates (DEHP)</td><td style="text-align: center;"><input type="checkbox"/> YES</td><td style="text-align: center;"><input checked="" type="checkbox"/> NO</td></tr> <tr> <td>Products of animal or biological origin</td><td style="text-align: center;"><input checked="" type="checkbox"/> YES</td><td style="text-align: center;"><input type="checkbox"/> NO</td></tr> </table> | Elements | Material | Dimensions | Sponge | Gelatin from porcine origin | 1x1x1cm | Presence of : | | | Latex | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO | Phthalates (DEHP) | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO | Products of animal or biological origin | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
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| Sponge | Gelatin from porcine origin | 1x1x1cm | | | | | | | | | | | | | | | | | |
| Presence of : | | | | | | | | | | | | | | | | | | | |
| Latex | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO | | | | | | | | | | | | | | | | | |
| Phthalates (DEHP) | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO | | | | | | | | | | | | | | | | | |
| Products of animal or biological origin | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO | | | | | | | | | | | | | | | | | |
| 2.9 | Field - Indications: Unknown | | | | | | | | | | | | | | | | | | |
| 3. Method of sterilizing | | | | | | | | | | | | | | | | | | | |
| | <p>Sterile : YES</p> <p>Sterilization method: Gamma Sterilisation (R)</p> | | | | | | | | | | | | | | | | | | |
| 4. Storage conditions | | | | | | | | | | | | | | | | | | | |

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| | <p>Normal conditions of storage: Store in a dry environment and at room temperature.</p> <p>Special precautions: Keep this product away from direct sunlight.</p> <p>Shelf life: 5 years</p> <p>Presence of temperature indicators: NO</p> |
| 5. Safety in use | |
| 5.1 | Technical security: N/A |
| 5.2 | Biosecurity: N/A |
| 6. Advices of use | |
| | <p>WARNING: Sterile content - Do not use if packaging is damaged -</p> <p>Do not re- sterilize – Single use product: destroy after use.</p> |
| 7. Additional product information | |
| | Single use: YES |
| 8. Related documents | |
| | Unknown |