

## Non sterile sleeves

### Technical data sheet - Medical Device

<b>1. Administrative information about the company</b>		<b>Date of issue : 01/10/2015</b>
<b>1.1</b>	<b>Name :</b> Hygitech SAS	
<b>1.2</b>	<b>Complete address :</b> 25 rue Bleue 75009 PARIS – FRANCE	<b>Phone:</b> +33 1 48 01 32 89 <b>Fax :</b> +33 1 48 01 32 80 <b>e-mail :</b> info@hygitech.fr <b>Web site :</b> www.hygitech.fr
<b>1.3</b>	<b>Contact information Materiovigilance :</b> Claudia Régnier	<b>Phone :</b> +33 1 45 91 31 82 <b>Fax :</b> +33 1 48 65 67 23 <b>e-mail :</b> qualite@hygitech.fr
<b>2. Information about the equipment</b>		
<b>2.1</b>	<b>Trade name:</b> Non sterile sleeves	
<b>2.2</b>	<b>Class of MD :</b> Class I <b>European Directive:</b> 93/42/EEC including Directive 2007/47/CE <b>According Annex n°</b> N/A <b>Notified body:</b> AUTO <b>Date of first launch on the UE market:</b> 2014_07 <b>Manufacturer :</b> Hygitech	
<b>2.3</b>	<p><b>Product description :</b></p> <p>HYGICOVER polyethylene protection sleeves enable you to cover hand pieces, cables, turbines and contra-angles. Effective barrier to fight against cross contamination, practical: Sleeves are easily separated one from another via the dispenser box. Resistant and easy to use.</p> <p>These products are solely intended for single use. Sleeves must to be changed after every patient.</p> <p>Protection sleeve for turbine 45 mm. Dimensions: 4.5x45 cm, Ø2.8 cm, conical end 1.5cm</p> <p>Protection sleeve for contra-angles, hand pieces and air/water syringes 55 mm Dimensions: 5.5x45 cm, Ø3.5 cm, conical end, 1.5cm</p>	
		

<b>2.4</b>	<b>Packaging :</b>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #f4a460;"> <th style="text-align: center;">Reference</th> <th style="text-align: center;">OU Order unit</th> <th style="text-align: center;">CARTON</th> <th style="text-align: center;">MOQ Minimum order quantity</th> </tr> </thead> <tbody> <tr> <td>HY-060</td> <td>Box of 250 sleeves on a roll</td> <td>Carton of 18 boxes</td> <td>Box of 250 sleeves on a roll</td> </tr> <tr> <td>HY-062</td> <td>Box of 250 sleeves on a roll</td> <td>Carton of 18 boxes</td> <td>Box of 250 sleeves on a roll</td> </tr> </tbody> </table> <b>Labelling :</b> Unknown	Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY-060	Box of 250 sleeves on a roll	Carton of 18 boxes	Box of 250 sleeves on a roll	HY-062	Box of 250 sleeves on a roll	Carton of 18 boxes	Box of 250 sleeves on a roll									
Reference	OU Order unit	CARTON	MOQ Minimum order quantity																			
HY-060	Box of 250 sleeves on a roll	Carton of 18 boxes	Box of 250 sleeves on a roll																			
HY-062	Box of 250 sleeves on a roll	Carton of 18 boxes	Box of 250 sleeves on a roll																			
<b>2.8</b>	<b>Composition of the product, dimensions and accessories :</b>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #f4a460;"> <th style="text-align: center;">Elements</th> <th style="text-align: center;">Materials</th> <th style="text-align: center;">Dimensions</th> </tr> </thead> <tbody> <tr> <td>Protection sleeve for turbine 45 mm.</td> <td>PVC</td> <td>4.5x45 cm, Ø2.8 cm 4.5x45 cm, Ø2.8 cm, conical end 1.5cm</td> </tr> <tr> <td>Protection sleeve for contra-angles, hand pieces and air/water syringes 55 mm</td> <td>PVC</td> <td>5.5x45 cm, Ø3.5 cm, conical end 1.5cm</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #f4a460;"> <th colspan="3" style="text-align: center;">Presence of :</th> </tr> </thead> <tbody> <tr> <td>Latex</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>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 type="checkbox"/> YES</td> <td style="text-align: center;"><input checked="" type="checkbox"/> NO</td> </tr> </tbody> </table>	Elements	Materials	Dimensions	Protection sleeve for turbine 45 mm.	PVC	4.5x45 cm, Ø2.8 cm 4.5x45 cm, Ø2.8 cm, conical end 1.5cm	Protection sleeve for contra-angles, hand pieces and air/water syringes 55 mm	PVC	5.5x45 cm, Ø3.5 cm, conical end 1.5cm	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 type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Elements	Materials	Dimensions																				
Protection sleeve for turbine 45 mm.	PVC	4.5x45 cm, Ø2.8 cm 4.5x45 cm, Ø2.8 cm, conical end 1.5cm																				
Protection sleeve for contra-angles, hand pieces and air/water syringes 55 mm	PVC	5.5x45 cm, Ø3.5 cm, conical end 1.5cm																				
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 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> NO <b>Sterilization method:</b> N/A																					
<b>4. Storage conditions</b>																						
	<b>Normal conditions of storage:</b> N/A <b>Special precautions:</b> N/A <b>Shelf life:</b> N/A <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>																						
	This product has been made exclusively as a single-use product - Destroy after use																					
<b>7. Additional product information</b>																						
	<b>Single use:</b> YES																					
<b>8. Related documents</b>																						
	Unknown																					