


Kit 3 instruments, sterile

Technical data sheet - Medical Device

1. Administrative information about the company		Date of issue : 15/12/2020									
1.1	Name : Hygitech SAS										
1.2	Complete address : 109 B Avenue Charles de Gaulle 92200 Neuilly-sur-Seine FRANCE	Phone: +33 1 48 01 32 89 Fax : +33 1 48 01 32 80 e-mail : info@hygitech.fr Web site : www.hygitech.fr									
1.3	Contact information Materiovigilance : Claudia Régnier	Phone : +33 1 45 91 31 82 Fax : +33 1 48 65 67 23 e-mail : qualite@hygitech.fr									
2. Information about the equipment											
2.1	Trade name: Kit 3 instruments, sterile										
2.2	Class of MD : Class ISTERILE European Directive: 93/42/EEC including Directive 2007/47/CE According Annex n° V Notified body: 1639 SGS BELGIUM Date of first launch on the UE market: 2010_05 Manufacturer : Hygitech										
2.3	Product description : Ideal for short procedures or simple patient visits. Packed in a transparent plastic peel pack tray, which provides easy identification of contents. Smart set: 3 pieces with tools on each side = 6 instruments <div style="text-align: center;">  </div>										
2.4	Packaging : <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #f4a460;"> <th style="padding: 5px;">Reference</th> <th style="padding: 5px;">OU Order unit</th> <th style="padding: 5px;">CARTON</th> <th style="padding: 5px;">MOQ Minimum order quantity</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">HY- 130012</td> <td style="padding: 5px;">Box of 20 units</td> <td style="padding: 5px;">Carton of 24 boxes of 20 units</td> <td style="padding: 5px;">1 box of 20 units</td> </tr> </tbody> </table> Labelling : Unknown			Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY- 130012	Box of 20 units	Carton of 24 boxes of 20 units	1 box of 20 units
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2.8	Composition of the product, dimensions and accessories : <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #ff8c00; color: white;"> <th style="text-align: center;">Elements</th> <th style="text-align: center;">Material</th> <th style="text-align: center;">Dimensions</th> </tr> </thead> <tbody> <tr> <td>Pair of tweezers</td> <td>Acier inoxydable</td> <td>L : 16 cm</td> </tr> <tr> <td>Mouth mirror</td> <td></td> <td>L :17 cm, angle :30°, diameter 20 mm</td> </tr> <tr> <td>Probe</td> <td>Acier inoxydable</td> <td>L : 10 cm</td> </tr> <tr> <td>Sterile bag</td> <td>Paper</td> <td>22 x 7,5 cm</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #ff8c00; color: white;"> <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	Material	Dimensions	Pair of tweezers	Acier inoxydable	L : 16 cm	Mouth mirror		L :17 cm, angle :30°, diameter 20 mm	Probe	Acier inoxydable	L : 10 cm	Sterile bag	Paper	22 x 7,5 cm	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
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2.9	Field - Indications: Unknown																											
3. Method of sterilizing																												
	Sterile : YES Sterilization method : Ethylene oxide (EO)																											
4. Storage conditions																												
	Normal conditions of storage: The product must be stored in a non-toxic room with a humidity rate under 80% and equipped with a ventilating system Special precautions: N/A Shelf life: 3 years Presence of temperature indicators: NO																											
5. Safety in use																												
5.1	Technical security: N/A																											
5.2	Biosecurity: N/A																											
6. Advices of use																												
	Refer to the manual for more information on the instructions for use, indications, precautions and contra-indications																											
7. Additional product information																												
	Single use: YES																											
8. Related documents																												
	Unknown																											