

## Sterile irrigation set HY-110001


### Technical data sheet - Medical Device

#### 1. Administrative information about the company

Date of issue : 01/10/2015

1.1	<b>Name :</b> Hygitech SAS	
1.2	<b>Complete address :</b> 109 bis avenue Charles de Gaulle, 92200 Neuilly-sur-Seine	<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
1.3	<b>Contact information</b> <b>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

#### 2. Information about the equipment

2.1	<b>Trade name:</b> Sterile irrigation set										
2.2	<b>Class of MD :</b> Class ISTERILE <b>European Directive:</b> 93/42/EEC including Directive 2007/47/CE <b>According Annex n° V</b> <b>Notified body:</b> 0120 SGS UK LIMITED <b>Date of first launch on the UE market:</b> 2010_05 <b>Manufacturer :</b> HYGITECH										
2.3	<b>Product description :</b> 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.  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.  Compatible with : <table><tr><td>FRIADENT</td><td>Frios unit S / Si</td></tr><tr><td>3i</td><td>Surgical unit</td></tr><tr><td>NOBELBIOCARE</td><td>80 / Osseo set 100 / 200 / Osseocare</td></tr><tr><td>STRAUMANN</td><td>Zimmer Dental / Lifecore centre pulse - Innova Corp.</td></tr><tr><td>W&amp;H</td><td>Implantmed</td></tr></table> <div></div>	FRIADENT	Frios unit S / Si	3i	Surgical unit	NOBELBIOCARE	80 / Osseo set 100 / 200 / Osseocare	STRAUMANN	Zimmer Dental / Lifecore centre pulse - Innova Corp.	W&H	Implantmed
FRIADENT	Frios unit S / Si										
3i	Surgical unit										
NOBELBIOCARE	80 / Osseo set 100 / 200 / Osseocare										
STRAUMANN	Zimmer Dental / Lifecore centre pulse - Innova Corp.										
W&H	Implantmed										

2.4	Packaging :	<table><tr><th>Reference</th><th>OU Order unit</th><th>CARTON</th><th colspan="2">MOQ Minimum order quantity</th></tr><tr><td>HY-110001</td><td>Box of 10 units</td><td>Carton of 10 boxes of 10 units</td><td colspan="2">1 box of 10 units</td></tr></table>				Reference	OU Order unit	CARTON	MOQ Minimum order quantity		HY-110001	Box of 10 units	Carton of 10 boxes of 10 units	1 box of 10 units																																																																																															
		Reference	OU Order unit	CARTON	MOQ Minimum order quantity																																																																																																								
HY-110001	Box of 10 units	Carton of 10 boxes of 10 units	1 box of 10 units																																																																																																										
		Labelling : Unknown																																																																																																											
2.8	Composition of the product, dimensions and accessories :	<table><tr><th>Elements</th><th>Material</th><th colspan="2">Dimension</th></tr><tr><td>Cap</td><td>Polyethylene</td><td colspan="2"></td></tr><tr><td>Spike</td><td>ABS</td><td colspan="2"></td></tr><tr><td>Tube 1</td><td>PVC</td><td colspan="2">OD=4,1mm ID=2,9 mm L=50 cm</td></tr><tr><td>Roller clamp</td><td>ABS</td><td colspan="2"></td></tr><tr><td>Connector</td><td>ABS</td><td colspan="2"></td></tr><tr><td>Silicone tube</td><td>Silicone</td><td colspan="2">OD=4,9mm ID=3,1 mm L=8 cm</td></tr><tr><td>Connector</td><td>ABS</td><td colspan="2"></td></tr><tr><td>Tube 2</td><td>PVC</td><td colspan="2">OD=4,1mm ID=2,9 mm L=22 cm</td></tr><tr><td>3-way stopcock</td><td>Polycarbonate &amp; Polyethylene</td><td colspan="2"></td></tr><tr><td>Cap</td><td>Polyethylene</td><td colspan="2"></td></tr><tr><td colspan="4">2 ways system</td></tr><tr><td>Luer lock Male</td><td>ABS</td><td colspan="2">ID=2,5mm</td></tr><tr><td>Tube 1</td><td>PVC</td><td colspan="2">OD=2,5mm ID=1,1 mm L=200 cm</td></tr><tr><td>Connector Y</td><td>PVC</td><td colspan="2">ID=2,5mm</td></tr><tr><td>Tube 2 (x2)</td><td>PVC</td><td colspan="2">OD=2,5mm ID=1,1 mm L=15 cm</td></tr><tr><td colspan="4">1 way system</td></tr><tr><td>Luer lock Male</td><td>ABS</td><td colspan="2">ID=2,5mm</td></tr><tr><td>Tube 1</td><td>PVC</td><td colspan="2">OD=2,5mm ID=1,1 mm L=200 cm</td></tr><tr><td colspan="4">Accessories</td></tr><tr><td>N-shape hook (x5)</td><td>Polyethylene</td><td colspan="2"></td></tr><tr><td>S-shape hook (x6)</td><td>Polyethylene</td><td colspan="2"></td></tr><tr><td colspan="4">Presence of :</td></tr><tr><td>Latex</td><td></td><td><input type="checkbox"/> YES</td><td><input checked="" type="checkbox"/> NO</td></tr><tr><td>Phthalates (DEHP)</td><td></td><td><input checked="" type="checkbox"/> YES</td><td><input type="checkbox"/> NO</td></tr><tr><td>Products of animal or biological origin</td><td></td><td><input type="checkbox"/> YES</td><td><input checked="" type="checkbox"/> NO</td></tr></table>				Elements	Material	Dimension		Cap	Polyethylene			Spike	ABS			Tube 1	PVC	OD=4,1mm ID=2,9 mm L=50 cm		Roller clamp	ABS			Connector	ABS			Silicone tube	Silicone	OD=4,9mm ID=3,1 mm L=8 cm		Connector	ABS			Tube 2	PVC	OD=4,1mm ID=2,9 mm L=22 cm		3-way stopcock	Polycarbonate & Polyethylene			Cap	Polyethylene			2 ways system				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		1 way system				Luer lock Male	ABS	ID=2,5mm		Tube 1	PVC	OD=2,5mm ID=1,1 mm L=200 cm		Accessories				N-shape hook (x5)	Polyethylene			S-shape hook (x6)	Polyethylene			Presence of :				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
		Elements	Material	Dimension																																																																																																									
		Cap	Polyethylene																																																																																																										
		Spike	ABS																																																																																																										
		Tube 1	PVC	OD=4,1mm ID=2,9 mm L=50 cm																																																																																																									
		Roller clamp	ABS																																																																																																										
		Connector	ABS																																																																																																										
		Silicone tube	Silicone	OD=4,9mm ID=3,1 mm L=8 cm																																																																																																									
		Connector	ABS																																																																																																										
		Tube 2	PVC	OD=4,1mm ID=2,9 mm L=22 cm																																																																																																									
		3-way stopcock	Polycarbonate & Polyethylene																																																																																																										
		Cap	Polyethylene																																																																																																										
		2 ways system																																																																																																											
		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																																																																																																									
		1 way system																																																																																																											
		Luer lock Male	ABS	ID=2,5mm																																																																																																									
		Tube 1	PVC	OD=2,5mm ID=1,1 mm L=200 cm																																																																																																									
		Accessories																																																																																																											
		N-shape hook (x5)	Polyethylene																																																																																																										
		S-shape hook (x6)	Polyethylene																																																																																																										
		Presence of :																																																																																																											
		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																																																																																																								
2.9	Field - Indications: Unknown																																																																																																												
3. Method of sterilizing																																																																																																													
	Sterile : YES Sterilization method: Ethylene Oxide (EO)																																																																																																												
4. Storage conditions																																																																																																													
	Normal conditions of storage: 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 Special precautions: Keep this product away from direct sunlight 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