

Isotonic saline solution

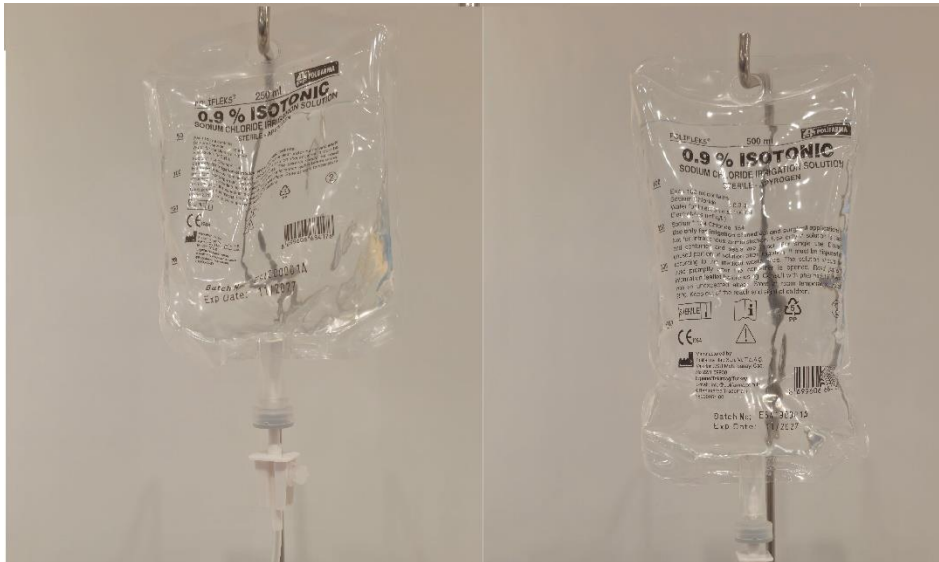
Technical data sheet - Medical Device

1. Administrative information about the company

Date of issue : 09/04/2025

1.1	Name : Hygitech SAS	
1.2	Complete address : 55 avenue Foch 75116 PARIS – FRANCE	Phone: +33 1 48 01 32 89 e-mail : info@hygitech.fr Web site : www.hygitech.fr
1.3	Contact information Materiovigilance : Said BOUTOUGHMAS	Phone : +33 1 45 91 31 82 e-mail : qualite@hygitech.fr

2. Information about the equipment

2.1	Trade name: Sterile irrigation set										
2.2	Class of MD : Class IIa European Directive: MDD 93/42/CEE Notified body: 1984 KIWA Manufacturer : Polifarma										
2.3	Product description : Saline water solution for irrigation. 0,9% sodium chloride concentration. 										
2.4	Packaging : <table border="1" data-bbox="341 1843 1450 1962"> <thead> <tr> <th>Reference</th><th>OU Order unit</th><th>MOQ Minimum order quantity</th></tr> </thead> <tbody> <tr> <td>PF-11000</td><td>Box of 40 units</td><td>1 Box of 40 units</td></tr> <tr> <td>PF-12000</td><td>Box of 25 units</td><td>1 Box of 25 units</td></tr> </tbody> </table> Labelling : Unknown		Reference	OU Order unit	MOQ Minimum order quantity	PF-11000	Box of 40 units	1 Box of 40 units	PF-12000	Box of 25 units	1 Box of 25 units
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2.8	Composition of the product, dimensions and accessories : <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="3" style="background-color: #ff4500; color: white; text-align: center;">Presence of :</th> </tr> <tr> <td style="width: 60%;">Latex</td> <td style="width: 20%; text-align: center;">☐ YES</td> <td style="width: 20%; text-align: center;">☒ NO</td> </tr> <tr> <td>Phthalates (DEHP)</td> <td style="text-align: center;">☐ YES</td> <td style="text-align: center;">☒ NO</td> </tr> <tr> <td>Products of animal or biological origin</td> <td style="text-align: center;">☐ YES</td> <td style="text-align: center;">☒ NO</td> </tr> </table>			Presence of :			Latex	☐ YES	☒ NO	Phthalates (DEHP)	☐ YES	☒ NO	Products of animal or biological origin	☐ YES	☒ NO
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2.9	Field - Indications: Unknown														
3. Method of sterilizing															
	Sterile : YES Sterilization method: Steam sterilization														
4. Storage conditions															
	Normal conditions of storage: Store in a dry environment and at room temperature 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														