
**APPLIMED****SA**

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

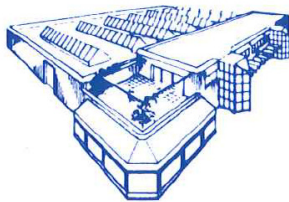
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PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Irrigation Cannula
I/2	General Description	Irrigation Cannula, curved, 90mm, 19G, Luer lock
I/3	GMDN N°	30889
I/4	Reference Number	8001773
I/5	Class	<input type="checkbox"/> I <input type="checkbox"/> Is <input checked="" type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 6
I/6	Notify Body	CE ₀₁₂₀
I/7	Composition Raw Material	Stainless Steel 304/Cr
I/8	Sterile	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If, yes <input checked="" type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging: 1 piece per peel pack
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	This medical device is a surgical instrument used for the cleaning and irrigation of the wound. Single use and transient Use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use, if the device is dirty or visual defects If packaging is damaged or open do not use. Sterile unless package is damaged.
II/4	Special requirement for use	n/a
II/5	Handling and storage conditions:	Standard conditions or atmospheric conditions

III- Supplementary information		
III/1	Compatibility with others medical devices (in the set)	n/a
III/2	Device contents animal substances	NO
III/3	Device contents medicinal substances	NO
III/4	Device comes into contact with substances	YES (usual substances used for treatment and cleaning of wounds)
III/5	Used with Accessories	NO
III/6	Used in combination with other Medical Device	NO



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IV- MANUFACTURING		
IV/1	Manufacturing Operations <div> <input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input checked="" type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input checked="" type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization </div>	1 pieces per peel pack 100 peel pack per box 10 box per cartons
IV/2	<u>Labelling: According to Directive 93/42/EEC</u> <u>Annex I § 13.3 and ISO 15223-1</u> <ul style="list-style-type: none"> Name and description of product Name and address of manufacturer LOT N° Article N° Expiry date Quantity Sterile Method of sterilisation Indication for single use Not use if the pack is opened CE 0120 	<div> Example of a label Aiguille mousse LL courbée 1 Aiguille mousse LL courbée, 90mm, 19G 100 Peelpacks/boîte 10 Boîtes/carton </div> <div> <div>REF 8001773</div> <div> 2018-12 </div> <div>LOT 13.12.05</div> </div> <hr/> <div> Stumpfe Kanüle LL 90 mm, 19G gebogen, Metall, einweg einzeln steril verpackt 100 Peelpacks/Schachtel 10 Schachteln/Karton </div> <div> Distribué par </div> <div> <div> </div> <div> Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis </div> <div> </div> <div> (01)07640103631331(17)181205(10)131205 </div> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)