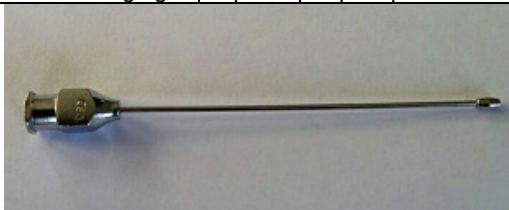
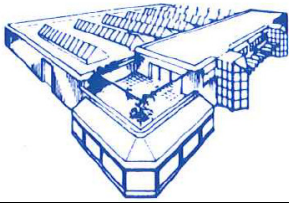


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Irrigation Cannula
I/2	General Description	Irrigation Cannula, Straight, 60mm, 19G
I/3	GMDN N°	30889
I/4	Reference Number	8001726
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 <sub>1639</sub>
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	Picturep	

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. The olive protects the tissues against the needle tip. 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



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

TEL : +41 (0) 21 948 92 74  
 FAX : +41 (0) 21 948 90 36  
 E-mail : info@applimed.ch  
 Website : www.applimed.ch

## IV- MANUFACTURING

<b>IV/1</b>	Manufacturing Operations	<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	1 pieces per peel pack  100 peel pack per box 10 box per cartons
<b>IV/2</b>	<p><u>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</u></p> <ul style="list-style-type: none"> <li>Name and description of product</li> <li>Name and address of manufacturer</li> <li>LOT N°</li> <li>Article N°</li> <li>Expiry date</li> <li>Quantity</li> <li>Sterile</li> <li>Method of sterilisation</li> <li>Indication for single use</li> <li>Not use if the pack is opened</li> <li>CE 1639</li> </ul>	<p>Example of a label</p>	
<b>IV/3</b>	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	