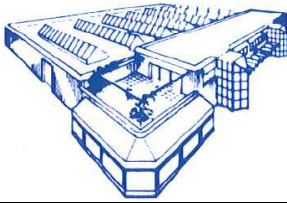


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Scissor
I/2	General Description	Scissor, sharp/shap, 14cm
I/3	GMDN N°	13502
I/4	Reference Number	8001716
I/5	Class	<input type="checkbox"/> I <input checked="" type="checkbox"/> Is <input type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 1
I/6	Notify Body	CE ₀₁₂₀
I/7	Composition Raw Material	Stainless Steel 420
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:	Cut the Suture or bandage. Alone, 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



Zone industrielle
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CH-1618 CHATEL-ST-DENIS
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FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

II/5	Handling and storage conditions:	Standard conditions or atmospheric conditions
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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

IV- MANUFACTURING

IV/1	Manufacturing Operations	<input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input checked="" type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	1 pieces per peel pack 50 peel packs per cartons
IV/2	<u>Labelling: According to Directive 93/42/EEC 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 style="text-align: right;">Example of a label</div> <p>Ciseaux 1 Ciseaux pointus/pointus, 14cm 50 Peelpacks/carton</p> <div style="text-align: right;"> REF 8001716 2018-09 LOT 13.09.19 </div> <div style="text-align: center; margin-top: 10px;"> <p>Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> <p>(01)07640103631928(17)180919(10)130919</p> </div>	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	

