APPLIMED SA

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

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PRODUCT DATA

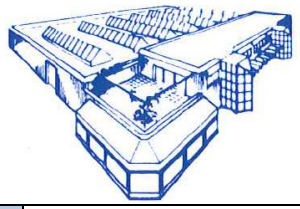
I-Product Description & Classification		
I/1	Designation	Scissor
I/2	General Description	Scissor, sharp/shap, 14cm
I/3	GMDN N°	13502
I/4	Reference Number	8001716
I/5	Class	☐ I ☒ Is ☐ IIa According to Directive 93/42/EEC - Annex IX, Rules 1
I/6	Notify Body	**CE**0120
I/7	Composition Raw Material	Stainless Steel 420
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ 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

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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

IV- MANUFACTURING			
IV/1	Manufacturing Operations	☒ peel pack ☐ pouches ☐ boxes ☒ cartons ☒ cleaning ☒ 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> • 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	Example of a label Ciseaux 1 Ciseaux pointus/pointus, 14cm 50 Peelpacks/carton REF 8001716 2018-09 LOT 13.09.19 CE 0120 STERILE EO Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis (01)07640103631928(17)180919(10)130919	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	