

APPLIMED

SA

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

I-Product Description & Classification		
I/1	Designation	Scissor
I/2	General Description	Scissor, sharp/blunt, 14cm
I/3	GMDN N°	13502
I/4	Reference Number	8001712
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	

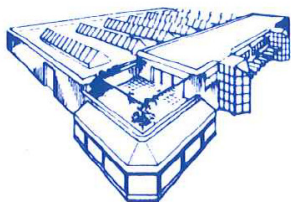
II- Description of use and operating of device		
II/1	Intended use/indication:	Cut the Suture or bandage. Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use, if the device is dirty or visual defects If packaging is damaged or open do not use. Sterile unless package is damaged.
II/4	Special requirement for use	n/a
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



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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 14cm, pointu/mousse 50 Peelpacks/carton REF 8001712  2020-09 LOT 15.09.07  0120 STERILE EO    Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis  (01) 07640103630525 (17) 200907 (10) 150907 SAD
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)