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	Curette
I/2	General Description	Curette, 14cm, head 4mm
I/3	GMDN N°	34980
I/4	Reference Number	8001750
I/5	Class	☐ I ☐ Is ☒ IIa According to Directive 93/42/EEC - Annex IX, Rules 6
I/6	Notify Body	**CE**0120
I/7	Composition Raw Material	Stainless Steel 410
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	

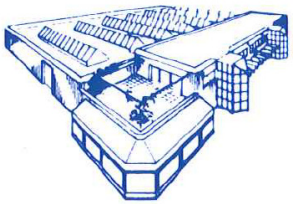
II- Description of use and operating of device		
II/1	Intended use/indication:	The scraping surgical instrument is used to obtain or remove tissue during dermal treatment. Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use If the 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 condition or atmospheric condition

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	No
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	☒ peel pack ☐ pouches ☐ boxes ☒ cartons ☒ cleaning ☒ sterilization	1 piece per peel pack 50 peel packs per cartons
IV/2	Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1 • Name and description of product • Name and address of manufacturer • LOT N° • Article N° • Year of manufacturing • Expiry date • Quantity • Sterile • Method of sterilisation • Indication for single use • Not use if the pack is opened • CE 0120	Example of a label Curette 1 Curette 14cm, tête 4mm 50 Peelpacks/carton REF 8001750 2019-01 LOT 14.01.30 CE 0120 STERILE EO Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis (01)07640103630181(17)190130(10)140130	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	