


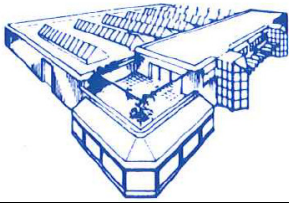
Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

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

PRODUCT DATA

I-Product Description & Classification	
I/1	Designation IRIS Scissor
I/2	General Description IRIS Scissor, 11.5cm
I/3	GMDN N° 35325
I/4	Reference Number 8001720
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 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 thin tissues during the surgery or to cutting the suture 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.









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

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

IV- MANUFACTURING		
IV/1	Manufacturing Operations <ul style="list-style-type: none"> <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 100 peel packs per cartons
IV/2	Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1 <ul style="list-style-type: none"> • 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 <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Ciseaux 1 Ciseaux Iris 11.5cm 100 Peelpacks/carton</p> <p style="text-align: right;">REF 8001720 2019-01 LOT 14.01.29</p> <p style="text-align: center;">      Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis SAD </p> <p style="text-align: center;">  (01)07640103630044(17)190129(10)140129 </p> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)