
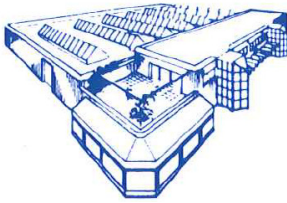


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Tweezers
I/2	General Description	Anatomic Tweezers, 14cm
I/3	GMDN N°	11777
I/4	Reference Number	8001731
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 ₁₆₃₉
I/7	Composition Raw Material	Stainless Steel 410
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	 IM1410 35/101 Pincette anatomique 14cm

II- Description of use and operating of device		
II/1	Intended use/indication:	Take the swab during the surgery 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
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



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

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
		<p>1 pieces per peel pack</p> <p>100 peel packs per cartons</p>
IV/2	<p>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</p> <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 	<p style="text-align: center;">Example of a label</p> <p>REF 8001731 LOT (10)21.06.09 (17)2026-05 Pincette anatomique 1 Pincette anatomique 14-14.5cm 100 Peelpacks/carton</p> <p>Anatomische Pinzette 1 Anatomische Pinzette 14-14,5cm 100 Peelpacks/Karton</p> <p>Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> <p>EC REP Dansu A/S Sandbakken 1-3 3600 Stenløse, Danmark</p>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)

