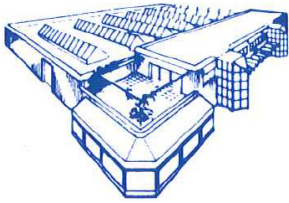


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Wood applicator
I/2	General Description	Applicator with Wooden Stick, 150x2.2mm, small cotton head
I/3	GMDN N°	34954
I/4	Reference Number	1101274
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 5
I/6	Notify Body	CE ₁₆₃₉
I/7	Composition Raw Material	100 % cotton and wooden stick
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: 5 pieces per peel pack
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	A device intended used to apply a substance (eg medication) to the Ear/Nose/throat (ENT) treatment and to care the superficial wound for absorption, barrier or compressing 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	Should not be use with Alcohol
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	Applimed has demonstrated compatibility with the following substances: - Water - Peroxide water (3%) - Betadine - Octenisept - Eosine - Merfen
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 checked="" type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	5 pieces per peel pack 100 peel pack per box 10 box per cartons
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° Year of manufacturing Quantity Sterile Method of sterilisation Indication for single use Not use if the pack is opened CE 1639 	<p style="text-align: right;">Example of a label</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>REF 1101274</p> <p>LOT (10)21.03.01 (17)2025-08</p> <p>Applicateur bois 150x2.2mm 5 Applicateurs, petite tête coton 100 Peelpacks/boîte 10 Boîtes/carton</p> <hr/> <p>Holzstäbchen 150x2.2mm kleiner Wattekopf 5 Stk/Peelpack 100 Peelpacks/Schachtel 10 Schachteln/Karton</p> </div> <div style="width: 50%; text-align: right;"> <p>UDI </p> <p>GTIN (01)07640103634462</p> <p>CE MD 1639</p> <p>STERILE EO</p> <p> </p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;"> <p> Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> </div> <div style="width: 50%; text-align: right;"> <p> Dansu A/S Sandbakken 1-3 3660 Stenløse, Danmark</p> <p>EC REP</p> </div> </div>	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	