

APPLIMED

SA

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

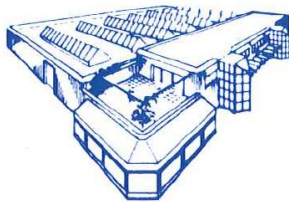
TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Wood applicator
I/2	General Description	Applicator with Wooden Stick, 150x2.2mm, small cotton head
I/3	GMDN N°	34954
I/4	Reference Number	1101250
I/5	Class	☐ I ☒ Is ☐ IIa According to Directive 93/42/EEC - Annex IX, Rules 4 and 5
I/6	Notify Body	CE ₁₆₃₉
I/7	Composition Raw Material	100 % cotton and wooden stick
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ Steam
I/9	First Packaging	Number of pieces in Packaging: 25 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 used 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



APPLIMED

SA

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	☒ peel pack ☐ pouches ☐ boxes ☒ cartons ☐ cleaning ☒ sterilization	25 pieces per peel pack 100 peel pack per carton
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° • Year of manufacturing • Expiry date • Quantity • Sterile • Method of sterilisation • Indication for single use • Not use if the pack is opened • CE 1639	Example of a label  REF 1101250 LOT (10)24.12.06 (17)2027-05 GERMANY GTIN (01)07640103637852 WA 1s 150 x 2.2 mm(25/PeelPack) Applikator Holzstab, Baumwollkopf Applicator wooden stick, cotton bud Aplicador hisopo de madera, cabeza de algodón Appicateur bâtonnet bois, tête coton Applikator træspind, bomuldshoved Applicatore bastoncino in legno, testa di cotone Aplikatorius su mediniu pagaliuku, medvilnės galvut Applicator houten staafje, katoenen tip Aplikacijska lesena palčka, bombaž Aplicador com haste de madeira, cabeça de algodão Vatové tyčinky, bavlněná hlavička UDI  Code 1030420 2500 Stück/pieces CE MD 1639   STERILE EO SD  Heinz Herenz Medizinbedarf GmbH Rudorffweg 10, 21031 Hamburg, Germany  Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis EC REP Dansu A/S Sandbakken 1-3 3660 Stenløse, Danmark	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	