

APPLIMED SA

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

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PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Wood applicator
I/2	General Description	Applicator with wooden stick, 150x3.0mm, big cotton head, American shape, sterile
I/3	GMDN N°	34954
I/4	Reference Number	1121463
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: 2 pieces per peel pack
I/10	Picture	

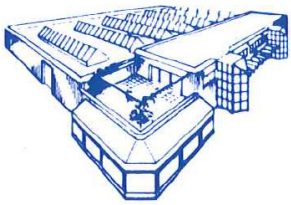
II- Description of use and operating of device		
II/1	Intended use/indication:	A device intended used to apply a substance (eg medication) to the Ear/Nose/throat (ENT) treatment and to care the superficial wound for absorption, barrier or compressing Alone, single use and transient Use (<60min)
II/2	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	Warning: fragile product (can break). Handle with Care 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

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IV- MANUFACTURING

IV/1	Manufacturing Operations	☒ peel pack ☒ pouches ☐ boxes ☒ cartons ☐ cleaning ☒ sterilization	2 pieces per peel pack 50 peel packs per pouch 5 pouches 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 usep • Not use if the pack is opened • CE 1639	Example of a label	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	

