**APPLIMED****SA**

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

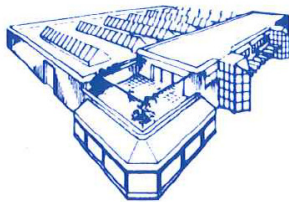
TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	PP applicator
I/2	General Description	Applicator with Polypropylene stick, 150x4 mm, American shape, Cotton big head
I/3	GMDN N°	33954
I/4	Reference Number	1521288
I/5	Class	☐ I ☒ Is ☐ IIa According to Directive 93/42/EEC - Annex IX, Rules 4 and 5
I/6	Notify Body	CE ₀₁₂₀
I/7	Composition Raw Material	100% cotton and Polypropylene 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	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/bags ☐ boxes ☒ cartons ☐ cleaning ☒ sterilization	2 pieces per peel pack 50 peel pack per bag 5 bag per carton
IV/2	Labelling: According to Directive 93/42 CEE Annex I § 13.3 and ISO 15223-1 - 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	Example of a label Applicateur PP 150x4.0 mm 2 Appicateurs, grosse tête américaine 50 Peelpacks/sachet 5 Sachets/carton REF 1521288  2018-12 LOT 13.12.13  0120 STERILE EO    Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis   (01)07640103630709(17)181213(10)131213	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	