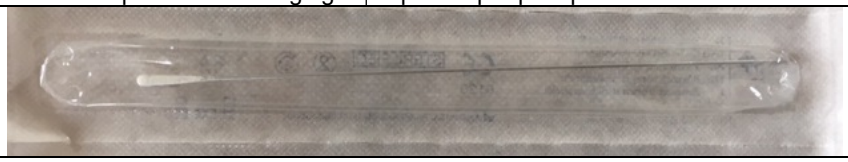


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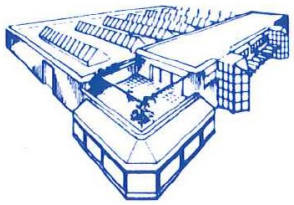
PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Metal applicator
I/2	General Description	Applicator with Aluminium Stick, 150x0.9 mm, Cotton head
I/3	GMDN N°	34954
I/4	Reference Number	1901199
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 (head), Aluminium Stick
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ Steam
I/9	First Packaging	Number of pieces in Packaging: 1 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 - 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	1 pieces per peel pack 100 peel pack per bag 25 bag per carton
IV/2	Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1 • 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	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	