
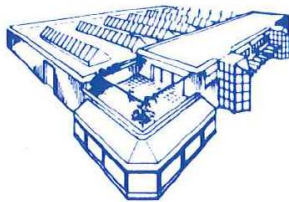


PRODUCT DATA

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	1102246
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 4 and 5
I/6	Notify Body	CE ₀₁₂₀
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: 2 piece 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	<input checked="" type="checkbox"/> peel pack <input checked="" type="checkbox"/> pouches <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization
		2 pieces per peel pack 100 peel packs per pouch 15 pouches per carton
IV/2	Labelling: According to Directive 93/42 CEE Annex I § 13.3 and ISO 15223-1 <ul style="list-style-type: none"> • 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 0120 	Example of a label <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p> Applicateur bois 150x2.2 mm petite tête coton 2 pcs/peel pack 100 peel packs/sachet 15 sachets/carton </p> <p style="text-align: right;"> REF 1102246 2018-11 LOT 13.11.28 </p> <p style="font-size: small;"> CE 0120 STERILE EO Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis SAD </p> <p style="font-size: x-small; text-align: center;">(01) 07640103631515(17) 181128(10) 131128</p> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)