
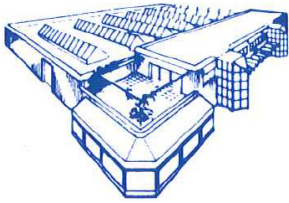


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Metal Applicator
I/2	General Description	Applicator with Aluminum Stick, 150x0.9 mm, Cotton head
I/3	GMDN N° CND N°	33954 M010103
I/4	Reference Number	1801183
I/5	Class	<input checked="" type="checkbox"/> I <input type="checkbox"/> Is <input type="checkbox"/> IIa According to Annex VIII of the Regulation 2017/745 (MDR), Rules 4 and 5
I/6	Notify Body	CE
I/7	Composition Raw Material	100% cotton (head) and Aluminum Stick
I/8	Sterile	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If, yes <input type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging: 100 piece per pouch
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.
II/4	Special requirement for use	Should not be use with Alcohol and Octenisept
II/5	Handling and storage conditions:	Standard conditions or atmosferic 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	<input type="checkbox"/> peel pack <input checked="" type="checkbox"/> pouches/bags <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input type="checkbox"/> sterilization	100 pieces per pouch 100 boxes per carton
IV/2	<p style="text-align: center;">Example of a label</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>REF 1801183 LOT 22.04.01</p> <p>Code 18-1183 2023-04</p> <p>10.000 Stk/pieces</p> <p>Applicateur aluminium, 150x0.9mm</p> <p>Applicateur aluminium, tête coton Applicator aluminium-stick, cotton bud Applikator Aluminium, Baumwollkopf Aplicador de aluminio, cabeza de algodón Applikator aluminium, bomuldshoved Applicatore in alluminio, testa di cotone Aplicador com haste de alumínio, cabeça de algodão Applikaattori alumiinia, puuvilla kärki Applicator aluminium, katoenen tip</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <small>Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</small> </div> <div style="text-align: center;"> <small>Dansu A/S Sandbakken 1-3 3660 Stenløse, Danmark</small> </div> <div style="text-align: center;"> <small>SD</small> </div> </div> <p>UDI <small>(01)07640103631478(17)230401(10)220401</small></p> </div>		
IV/3	Place of sterilisation:	n/a	