
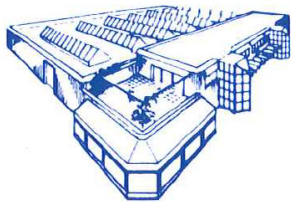


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	PP Applicator
I/2	General Description	Applicator with Polypropylene Stick, 150x4 mm, Big Cotton head, American Shape
I/3	GMDN N° CND N°	33954 M010103
I/4	Reference Number	1422280
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	<b>CE</b>
I/7	Composition Raw Material	100% cotton (head) and Polypropylene 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:   50 pieces per bag
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
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



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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

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
		50 pieces per bag  20 bags 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><b>REF</b> 1422280 <b>LOT</b> 21.04.19</p> <p> 2026-03</p> <p><b>1000 Stk/pieces</b></p> <p><b>Applicateur PP 150x4.0mm</b></p> <p>Applicateur grosse tête continentale            Applicator bighead, continental shape            Applikator Kontinentalform mit großem Kopf            Aplicador forma continental de cabeza grande            Applikator stort hoved kontinental form            Applicatore a testa grande, forma continentale            Aplicador formato continental de cabeça grande            Applicator grote kop continentale vorm</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 Steriløse, Danmark</small> </div> <div style="text-align: center;">   <small>DS</small> </div> </div> <p><b>UDI</b> </p> <p>(01)07640103632345(17)260319(10)210419</p> </div>	
IV/3	Place of sterilisation:	n/a