APPLIMED SA

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

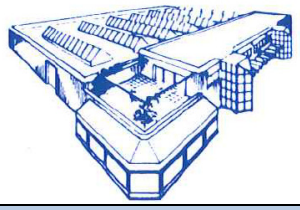
TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

PRODUCT DATA

I-Product Description & Classification			
I/1	Designation	Wood Applicator	
I/2	General Description	Applicator with Wooden Stick, 150x2.5mm, Big Cotton head, American Shape	
I/3	GMDN N° CND N°	33954 M010103	
I/4	Reference Number	1021292	
I/5	Class	☒ I ☐ Is ☐ 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 Wooden Stick	
I/8	Sterile	☐ Yes ☒ No If, yes ☐ ETO ☐ Gamma ☐ Steam	
I/9	First Packaging	Number of pieces in Packaging:	50 pieces 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	Warning: fragile product (can break). Handle with Care Should not be use with Alcohol
II/5	Handling and storage conditions:	Standard conditions or atmospheric conditions

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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

IV- MANUFACTURING			
IV/1	Manufacturing Operations	☐ peel pack ☒ pouches/bags ☐ boxes ☒ cartons ☐ cleaning ☐ sterilization	50 pieces per pouch 20 pouches per carton
IV/2	Example of a label		
IV/3	Place of sterilisation:	n/a	