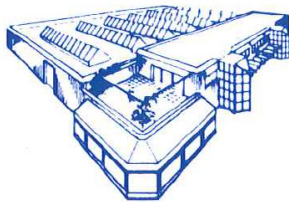


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	PS applicator
I/2	General Description	Applicator with Polystyrene stick, 140x4mm, cross blue moss
I/3	GMDN N°	33954
I/4	Reference Number	1251155
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 <sub>0120</sub>
I/7	Composition Raw Material	VITAPOL VPPT-2538 and Polystyrene 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 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	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 <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> peel pack</li> <li><input type="checkbox"/> pouches/bags</li> <li><input type="checkbox"/> boxes</li> <li><input checked="" type="checkbox"/> cartons</li> <li><input type="checkbox"/> cleaning</li> <li><input checked="" type="checkbox"/> sterilization</li> </ul>	2 pieces per peel pack  100 peel pack 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"> <li>Name and description of product</li> <li>Name and address of manufacturer</li> <li>LOT N°</li> <li>Article N°</li> <li>Expiry date</li> <li>Quantity</li> <li>Sterile</li> <li>Method of sterilisation</li> <li>Indication for single use</li> <li>Not use if the pack is opened</li> <li>CE 0120</li> </ul>	Example of a label <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>               Applicateur PS choc 140x4 mm <span style="float: right;"><b>REF</b> 1251155</span>                tête mousse bleue                2 pcs/peel pack <span style="float: right;"> 2019-11</span>                100 peel packs/carton <span style="float: right;"><b>LOT</b> 14.11.05</span> </p> <div style="text-align: center; margin-top: 10px;"> <p style="font-size: small;">               Applimed SA                Pra de Plan 1                CH-1618 Châtel-St-Denis             </p> </div> <p style="text-align: center; font-size: x-small;">               (01) 07640103630648(17) 191105(10) 141105             </p> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)