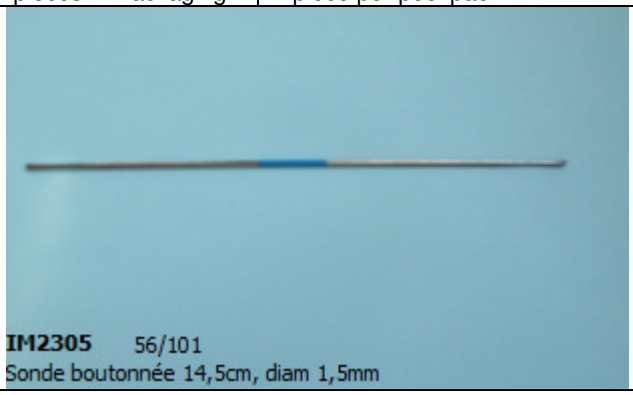
APPLIMED SA

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PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Probe
I/2	General Description	Buttoned Probe, 14.5cm, diameter = 1.5mm
I/3	GMDN N°	32870
I/4	Reference Number	8001711
I/5	Class	☐ I ☐ Is ☒ IIa According to Directive 93/42/EEC - Annex IX, Rules 6
I/6	Notify Body	**CE**1639
I/7	Composition Raw Material	Stainless Steel 410
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ Steam
I/9	First Packaging	Number of pieces in Packaging: 1 piece per peel pack
I/10	Picture	

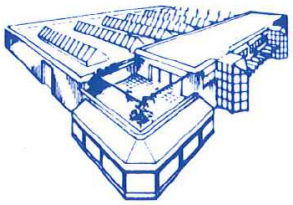
II- Description of use and operating of device		
II/1	Intended use/indication:	A device intended to be used for exploring sinuses or other cavities or wounds. This device has no measuring function. Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication 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	n/a
II/5	Handling and storage conditions:	Standard condition or atmospheric condition

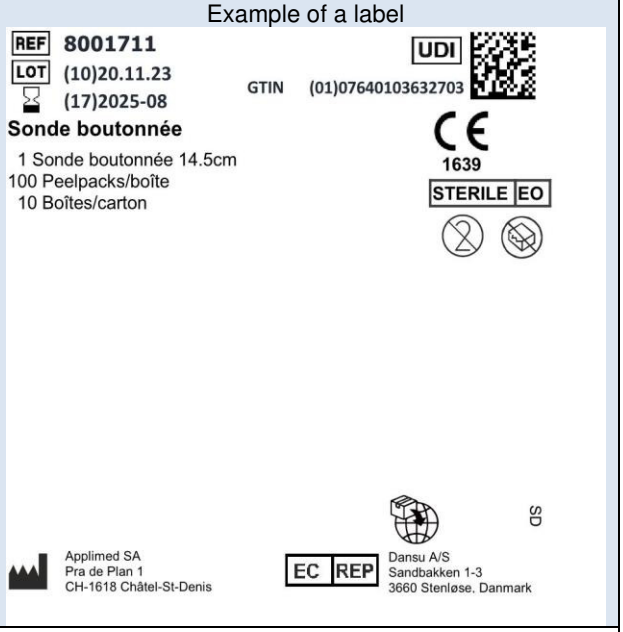
III- Supplementary information		
III/1	Compatibility with others medical devices (in the set)	n/a
III/2	Device contents animal substances	No
III/3	Device contents medicinal substances	No
III/4	Device comes into contact with substances	No
III/5	Used with Accessories	No
III/6	Used in combination with other Medical Device	No

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IV- MANUFACTURING			
IV/1	Manufacturing Operations	☒ peel pack ☐ pouches ☒ boxes ☒ cartons ☒ cleaning ☒ sterilization	1 pieces per peel pack 100 peel packs per box 10 boxes per cartons
IV/2	<u>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</u> • 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 1639	Example of a label  	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	