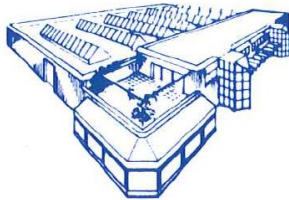


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Care Sets
I/2	General Description	Set : Sterile
I/3	GMDN N°	40247
I/4	Reference Number	8001814
I/5	Class	<input type="checkbox"/> I <input type="checkbox"/> Is <input checked="" type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 6
I/6	Notify Body	CE ₁₆₃₉
I/7	Composition Raw Material	1 Scissors, 14cm, blunt/Sharp 1 Anatomic tweezers, 14-14.5cm
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: 15 peel packs per box
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	Set that contains all the various instruments for the clean or ablation of suture or pose a patch around the wound. Alone, single use and transient use (<60min)
II/2	User:	Medical staff and Professional
II/3	Contraindication of use	No recognized contraindication
II/4	Special requirement for use	n/a
II/5	Handling and storage conditions:	Standard condition or atmospheric condition







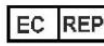
III- Supplementary information		
III/1	Compatibility with others medical devices	YES
III/2	Device contents animal substances	NO
III/3	Device contents medicinal substances	NON
III/4	Device comes into contact with substances	YES
III/5	Used with Accessories	NO
III/6	Used in combination with other Medical Device	NO



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IV- MANUFACTURING

IV/1	Manufacturing Operations	<input type="checkbox"/> peel pack <input type="checkbox"/> pouches <input checked="" type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	15 peel packs per box 4 boxes per cartons
IV/2	<p><u>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</u></p> <ul style="list-style-type: none"> 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 	<p>Example of a label</p> <p>REF 8001814 Code IN151503   LOT (10)21.04.23 GTIN (01)07640103631003 (17)2026-03</p> <p>Set Stérile 1 Ciseaux 14cm, pointu/mousse 1 Pincette anatomique 14-14.5cm 15 Peelpacks/carton 4 Cartons/carton</p> <p> STERILE EO </p> <hr/> <p>Steriles Set 1 Schere 14cm, spitz/stumpf 1 Anatomische Pinzette 14-14,5cm 15 Peelpacks/Karton 4 Kartons/Karton</p> <p></p> <p> Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> <p> Dansu A/S Sandbakken 1-3 3660 Stenløse, Danmark</p>	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	