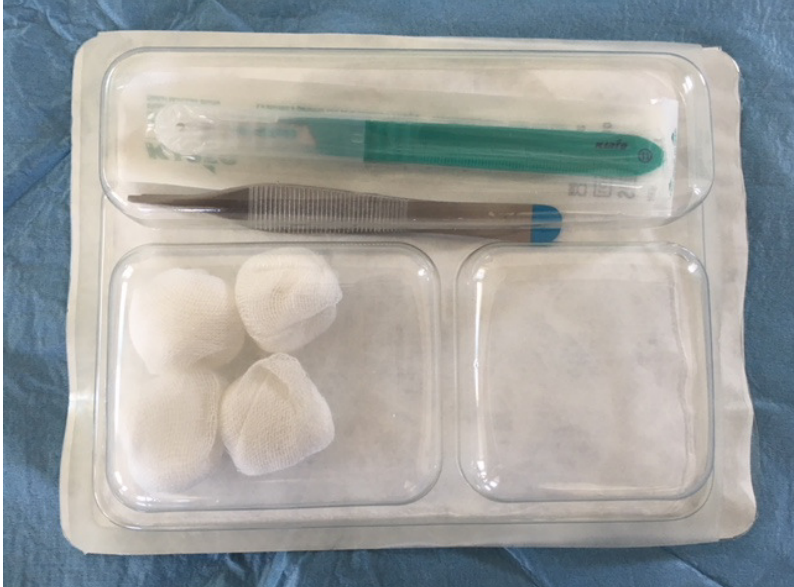
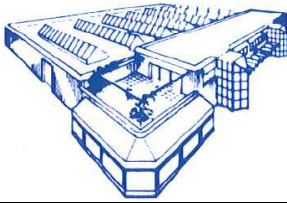


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Ablation Suture Sets
I/2	General Description	Set : Ablation Suture n°1
I/3	GMDN N°	40247
I/4	Reference Number	4909936
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 5 or 6
I/6	Notify Body	CE ₁₆₃₉
I/7	Composition Raw Material	4 Woven Gauze Balls Ø2.5-3cm 1 Tweezer "Adson" 12cm, Blunt 1 Disposable Scalpel n° 11
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: 36 sets per carton
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	Set that contains all the various instruments for only ablation of suture or remove the staple. 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



Zone industrielle
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Website : www.applimed.ch

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

IV- MANUFACTURING		
IV/1	Manufacturing Operations <input type="checkbox"/> peel pack <input type="checkbox"/> pouches <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	36 sets per cartons
IV/2	<u>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</u> <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 	Example of a label <p> REF 4909936 LOT (10)21.05.06 (17)2025-08 Set ablation suture n° 1 4 Boules tissées Ø2.5-3cm 1 Pincette Adson 12cm, mousse 1 Lame de bistouri n° 11 36 Sets/carton </p> <p> UDI GTIN (01)07640103633489 CE MD 1639 STERILE EO </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 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)