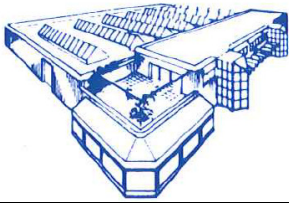


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Care Sets
I/2	General Description	Set : Bandage 10
I/3	GMDN N°	40247
I/4	Reference Number	4908019
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 5 and 6
I/6	Notify Body	CE ₀₁₂₀
I/7	Composition Raw Material	1 Tweezer, 13cm, blue 1 Tweezer, 13cm green 6 Woven Gauze Ball Ø 3 cm 2 Non-woven Compresses, 7.5x7.5cm 1 Drape, 50x50cm
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 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	YES



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Website : www.applimed.ch

	with substances	
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"> <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 0120 	Example of a label <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <p style="text-align: right;">SV032600</p> <p><i>Kuhn und Bieri</i></p> <p>1 Pincette 13cm, bleue 1 Pincette 13cm, verte 6 Boules tissées Ø 2.5-3cm 2 Compresses non tissées 7.5x7.5cm 1 Champ 50x50cm 36 Sets/carton</p> <hr/> <p>VERBANDSET 10 (Plastik)</p> <p>2 Pinzetten anatomisch (Plastik) REF 4908019 6 Gazerundtupfer Ø 3 cm 2 Vlieskompressen 7.5x7.5 cm 2018-11 1 Abdecktuch 45x45 cm 36 Sets/Karton LOT 13.11.04</p> <p style="font-size: small;">Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnbieteri.ch Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis SAD</p> <p> STERILE EO </p> <p style="font-size: x-small;">0120</p> </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)