
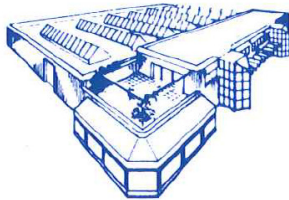


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Care Sets
I/2	General Description	Set : Bandage
I/3	GMDN N°	40247
I/4	Reference Number	4908018
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 <sub>0120</sub>
I/7	Composition Raw Material	1 Anatomic Tweezer (plastic) 5 woven Gauze Ball Ø 3 cm
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



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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"> <li>Name and description of product</li> <li>Name and address of manufacturer</li> <li>LOT N°</li> <li>Article N°</li> <li>Year of manufacturing</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 <b>SET DE PANSEMENT 3</b> 1 Pincette 13cm 5 Boules tissées Ø2.5-3cm 36 Sets/carton <b>VERBANDSET 3 (Plastik)</b> 1 Pinzette anatomisch (Plastik) 5 Gazerundtupfer Ø 3 cm 36 Sets/Karton Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnbieteri.ch      Applied SA Pra de Plan 1 CH-1618 Châtel-St-Denis
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)