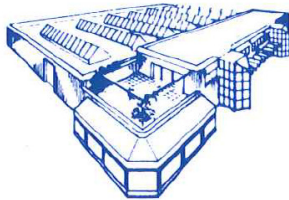


PRODUCT DATA

| I-Product Description & Classification | | |
|--|--------------------------|---|
| I/1 | Designation | Care Sets |
| I/2 | General Description | Set : Bandage 18 |
| I/3 | GMDN N° | 40247 |
| I/4 | Reference Number | 4908016 |
| 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 and 6 |
| I/6 | Notify Body | CE ₀₁₂₀ |
| I/7 | Composition Raw Material | 2 Anatomic Tweezer, 14-14.5cm 1 Scissors, sharp/blunt, 14cm 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 |



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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"> 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;"> <p>Set Pansement 18 2 Pincettes anatomiques 14-14.5cm 1 Ciseaux 14cm, pointu/mousse 1 Champ 50x50cm 36 Sets/carton</p> <p style="text-align: right;">IN151703</p>  </div> <hr/> <p>VERBANDWECHSEL-SET 18 (Stahl) 1 dreiteiliges steif Blister (gebraucht als Schälchen) 2 Pinzetten anatomisch 14-14.5cm (Stahl) 1 Schere stumpf/spitz 14cm (Stahl) 1 Abdecktuch 50x50cm 36 Sets/Karton</p> <p style="text-align: right;"> <input type="checkbox"/> REF 4908016 <input type="checkbox"/> 2022-10 <input type="checkbox"/> LOT 17.10.05 </p> <p>Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnundbieri.ch Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis</p> <div style="display: flex; align-items: center;">       </div> <p>0120</p> |
| IV/3 | Place of sterilisation: | ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande) |