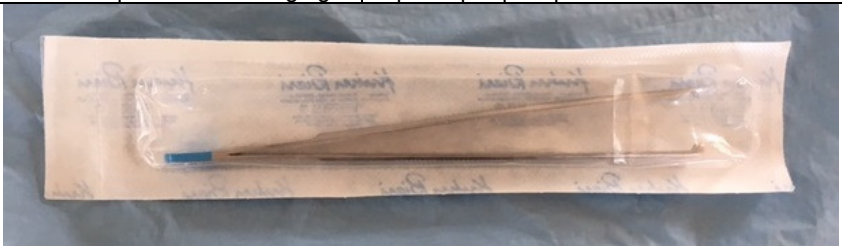
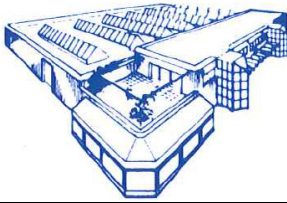


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Tweezers
I/2	General Description	Surgical Tweezers, 14cm
I/3	GMDN N°	37098
I/4	Reference Number	8001923
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 <sub>0120</sub>
I/7	Composition Raw Material	Stainless Steel 410
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:   1 piece per peel pack
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	Caught and take the tissues or to open and close the wound during the suture Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use If the device is dirty or visual defects If packaging is damaged or open do not use. Sterile unless package is damaged.
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 (in the set)	n/a
III/2	Device contents animal substances	No
III/3	Device contents medicinal substances	No
III/4	Device comes into contact with substances	No
III/5	Used with Accessories	No
III/6	Used in combination with other Medical Device	No



Zone industrielle  
 Route de Pra de Plan 1  
 CH-1618 CHATEL-ST-DENIS  
 Switzerland

TEL : +41 (0) 21 948 92 74  
 FAX : +41 (0) 21 948 90 36  
 E-mail : info@applimed.ch  
 Website : www.applimed.ch

## IV- MANUFACTURING

<b>IV/1</b>	Manufacturing Operations	<input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input checked="" type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input checked="" type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	1 pieces per peel pack  25 peel packs per box 4 boxes per carton
<b>IV/2</b>	<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>	<p style="text-align: right;">Example of a label</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p><b>Pincette</b>            1 Pincette chirurgicale 14cm            25 Peelpacks/carton            4 Cartons/carton</p> <p><b>Pinzette chirurgisch 14 cm</b>            1 Stk/Peelpack            25 Peelpacks/Schachtel</p> <p>Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnbieteri.ch</p> </div> <div style="width: 35%; text-align: right;"> <p><b>IN150106</b></p>   <p><b>REF</b> 8001923   2018-09  <b>LOT</b> 13.09.19</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 30%;">      </div> <div style="width: 40%; font-size: small;">       Applimed SA        Pra de Plan 1        CH-1618 Châtel-St-Denis     </div> <div style="width: 20%; text-align: right; font-size: small;">       SAD     </div> </div>	
<b>IV/3</b>	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	