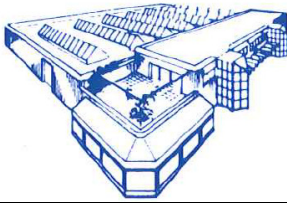


## PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Woven Ball
I/2	General Description	Woven Ball, diameter 2.5 cm
I/3	GMDN N°	34969
I/4	Reference Number	4102002
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 4
I/6	Notify Body	CE <sub>0120</sub>
I/7	Composition Raw Material	100% Cotton
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: 5 pieces per peel pack
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	A device that is intended to be applied with pressure to body surface to provide medication or to help control bleeding. 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 conditions or atmospheric conditions

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	YES (usual substances used for treatment and cleaning of wounds)
III/5	Used with Accessories	NO
III/6	Used in combination with other Medical Device	NO



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## IV- MANUFACTURING

<b>IV/1</b>	Manufacturing Operations	<input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches/bags <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	5 pieces per peel pack  80 peel pack per carton
<b>IV/2</b>	<u>Labelling: According to Directive 93/42 CEE 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>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: 70%;"> <p><b>Boule tissée</b>            5 Boules tissées Ø2.5-3cm            80 Peelpacks/carton</p> </div> <div style="width: 25%;"> <p><b>REF</b> 4102002</p> <p> 2020-04</p> <p><b>LOT</b> 17.04.26</p> </div> </div> <div style="text-align: center; margin-top: 10px;"> <p>Applimed SA        Pra de Plan 1        CH-1618 Châtel-St-Denis <sup>CH</sup></p> <p>(01)07640103637289(17)200426(10)170426</p> </div>	
<b>IV/3</b>	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	