
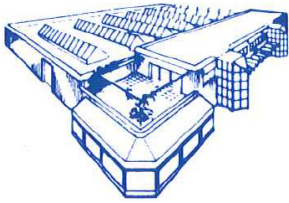


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Non-Woven Compress
I/2	General Description	Non-Woven Compress, 10x20cm, 4 ply
I/3	GMDN N°	34969
I/4	Reference Number	4702115
I/5	Class	<input checked="" type="checkbox"/> I <input type="checkbox"/> Is <input type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 4
I/6	Notify Body	CE
I/7	Composition Raw Material	Viscose/polyester
I/8	Sterile	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If, yes <input type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging: 100 pieces per pouch
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.
II/4	Special requirement for use	n/a
II/5	Handling and storage conditions:	Standard conditions or atmospheric conditions

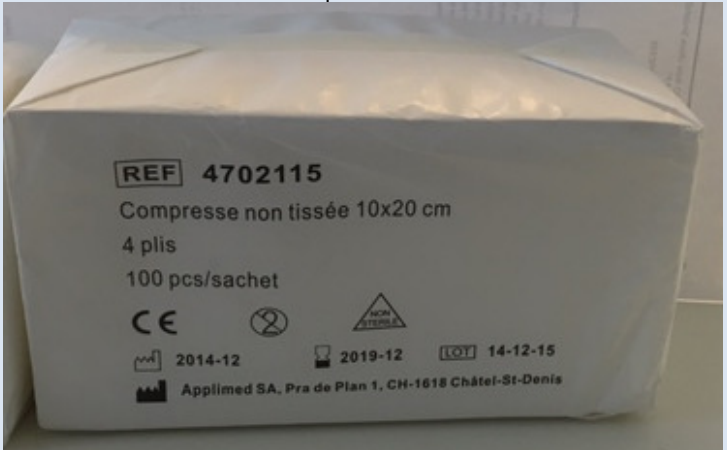
III- Supplementary information		
III/1	Compatibility with others medical devices (in the set)	n/a
III/2	Device contents animal substances	NO
III/3	Device contents medicinal substances	NO
III/4	Device comes into contact with substances	YES (usual substances used for treatment and cleaning of wounds)
III/5	Used with Accessories	NO
III/6	Used in combination with other Medical Device	NO



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IV- MANUFACTURING

IV/1	Manufacturing Operations	<input type="checkbox"/> peel pack <input checked="" type="checkbox"/> pouches/bags <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input type="checkbox"/> sterilization	100 pieces per pouch 50 peel pack per carton
IV/2	<u>Labelling: According to Directive 93/42 CEE 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° Expiry date Quantity Non-Sterile symbol Indication for single use CE 		Example of a label 
IV/3	Place of sterilisation:	n/a	