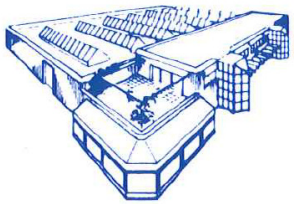

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Website : www.applimed.ch

PRODUCT DATA

I-Product Description & Classification			
I/1	Designation	Non-Woven Compress	
I/2	General Description	Non-Woven Compress, 5x5 cm, 40 gr, 4 plies	
I/3	GMDN N°	34969	
I/4	Reference Number	4801145	
I/5	Class	☐ I ☒ Is ☐ IIa According to Directive 93/42/EEC - Annex IX, Rules 4	
I/6	Notify Body	**CE**0120	
I/7	Composition Raw Material	100% Cotton	
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ Steam	
I/9	First Packaging	Number of pieces in Packaging:	2 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

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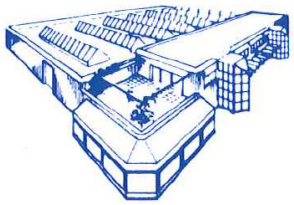
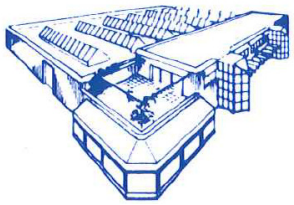


III- Supplementary information		
III/1	Compatibility with others medical devices (in the set)	n/a
III/2	Device contents animal substances	NO
III/3	Device contents medicinal substances	NO
III/4	Device comes into contact with substances	YES (usual substances used for treatment and cleaning of wounds)
III/5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

IV- MANUFACTURING			
IV/1	Manufacturing Operations	☒ peel pack ☐ pouches/bags ☒ boxes ☒ cartons ☐ cleaning ☒ sterilization	2 pieces per peel pack 90 peel pack per box 27 box per carton
IV/2	<u>Labelling: According to Directive 93/42 CEE Annex I § 13.3 and ISO 15223-1</u> • Name and description of product • Name and address of manufacturer • LOT N° • Article N° • Expiry date • Quantity • Sterile • Method of sterilisation • Indication for single use • Not use if the pack is opened • CE 0120	Example of a label 
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	



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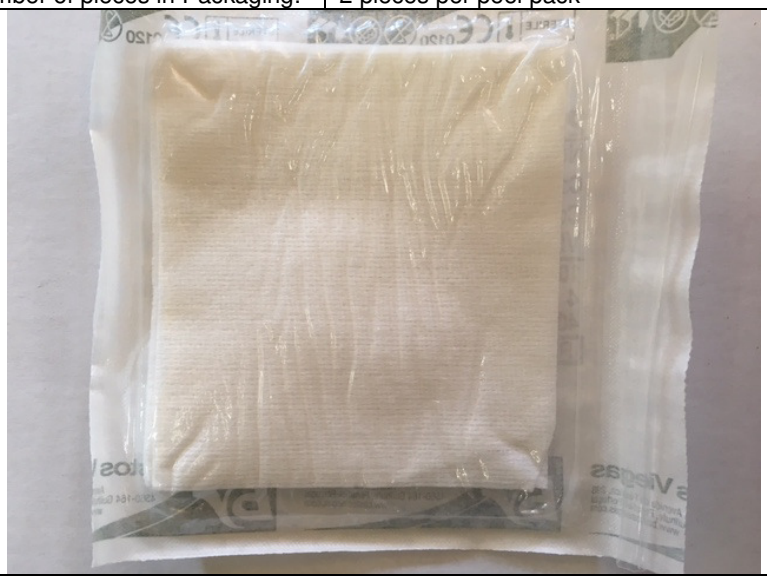
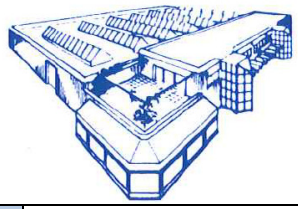
PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Non-Woven Compress
I/2	General Description	Non-Woven Compress, 10x10 cm, 40 gr, 4 layers
I/3	GMDN N°	34969
I/4	Reference Number	4801147
I/5	Class	☐ I ☐ Is ☒ IIa According to Directive 93/42/EEC - Annex IX
I/6	Notify Body	**CE$_{0120}$ (legal manufacturer : Bastos Viegas SA)**
I/7	Composition Raw Material	Viscose/Polyester
I/8	Sterile	☒ Yes ☐ No If, yes ☐ ETO ☐ Gamma ☒ Steam
I/9	First Packaging	Number of pieces in Packaging: 2 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:	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefor normal condition of medical device storage shall apply.

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



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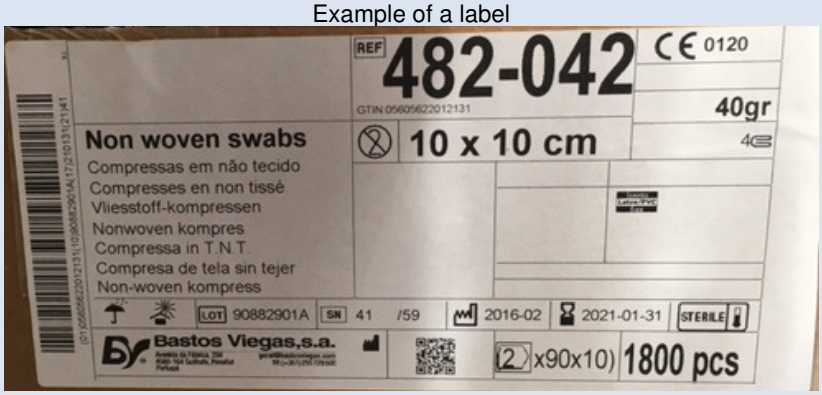
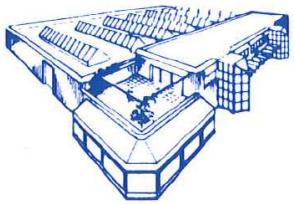
III/4	Device comes into contact with substances	YES (usual substances used for treatment and cleaning of wounds)
III/5	Used with Accessories	NO
III/6	Used in combination with other Medical Device	NO

IV- MANUFACTURING

IV/1	Manufacturing Operations	☒ peel pack ☐ pouches/bags ☒ boxes ☒ cartons ☐ cleaning ☒ sterilization	2 pieces per peel pack 50 peel pack per box 24 box per carton
IV/2	<u>Labelling: According to Directive 93/42 CEE Annex I § 13.3 and ISO 15223-1</u> • Name and description of product • Name and address of manufacturer • LOT N° • Article N° • Expiry date • Quantity • Sterile • Method of sterilisation • Indication for single use • CE 0120	Example of a label 	
IV/3	Distributor	By Applimed SA	



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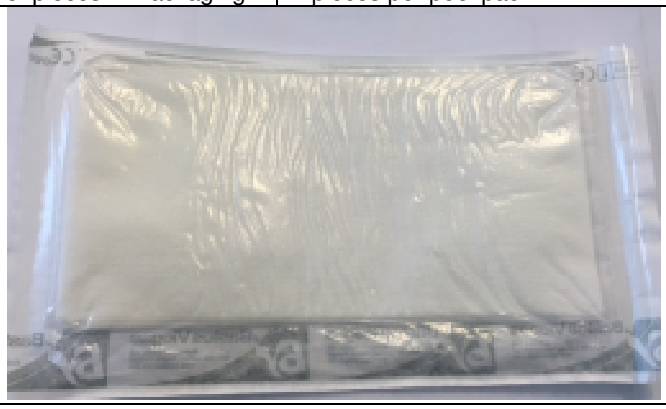
PRODUCT DATA

I-Product Description & Classification			
I/1	Designation	Non-Woven Compress	
I/2	General Description	Non-Woven Compress, 10x20 cm, 4 plies. 40gr	
I/3	GMDN N°	34969	
I/4	Reference Number	4801148	
I/5	Class	☐ I ☐ Is ☒ IIa According to Directive 93/42/EEC - Annex IX	
I/6	Notify Body	**CE$_{0120}$ (legal manufacturer : Bastos Viegas SA)**	
I/7	Composition Raw Material	Viscose/Polyester	
I/8	Sterile	☒ Yes ☐ No If, yes ☐ ETO ☐ Gamma ☒ Steam	
I/9	First Packaging	Number of pieces in Packaging:	2 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:	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefor normal condition of medical device storage shall apply.

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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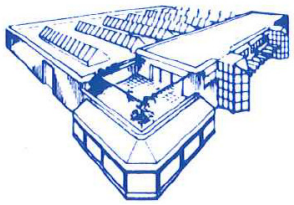

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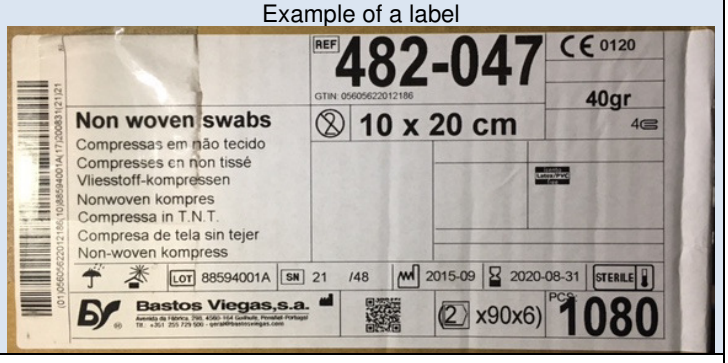
IV- MANUFACTURING			
IV/1	Manufacturing Operations	☒ peel pack ☐ pouches/bags ☒ boxes ☒ cartons ☐ cleaning ☒ sterilization	2 pieces per peel pack 90 peel packs per box 3 boxes per carton
IV/2	<u>Labelling: According to Directive 93/42 CEE Annex I § 13.3 and ISO 15223-1</u> • Name and description of product • Name and address of manufacturer • LOT N° • Article N° • Expiry date • Quantity • Sterile • Method of sterilisation • Indication for single use • CE 0120	Example of a label 	
IV/3	Distributor	By Applimed SA	