


APPLIMED

SA

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

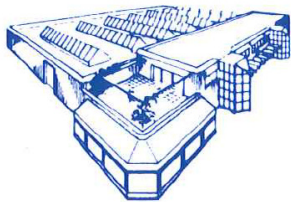
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PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Haemostatic Forceps
I/2	General Description	Haemostatic forceps, 12,5 cm, "Mosquitos"
I/3	GMDN N°	35081
I/4	Reference Number	8001705
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 ₀₁₂₀
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:	Clamp tissues or Swabs 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









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IV- MANUFACTURING		
IV/1	Manufacturing Operations <input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input checked="" type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization	1 pieces per peel pack 50 peel packs 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 	<div>Example of a label</div> <div> Pince Mosquito 1 Pince Mosquito 12.5cm 50 Peelpacks/carton </div> <div> REF 8001705  2018-07 LOT 13.07.13 </div> <div>  0120 STERILE EO    </div> <div>  (01)08435263809213(17)180600(10)130618 </div> <div> Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis </div>
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)