

APPLIMED

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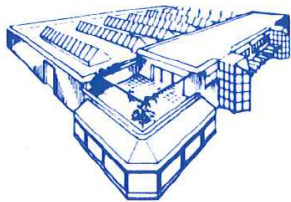
Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

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

PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Haemostatic Forceps
I/2	General Description	Haemostatic forceps, 12,5 cm, curved, "Mosquitos"
I/3	GMDN N°	35081
I/4	Reference Number	8001702
I/5	Class	☐ I ☐ Is ☒ 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	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ 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



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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	No
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 ☐ boxes ☒ cartons ☒ cleaning ☒ sterilization	1 pieces per peel pack 50 peel packs per cartons
IV/2	Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1 - 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	Example of a label Pince Mosquito 1 Pince Mosquito 12.5cm, courbée 50 Peelpacks/carton REF 8001702 EXP 2020-09 LOT 15.09.07 0120 STERILE EO (01)07640103630167(17)200907(10)150907 Applimed SA Pra de Plan 1 CH-1618 Châtel-St-Denis SAD	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135-1, By CSSR (Centre de sterilisation de Suisse Romande)	