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PRODUCT DATA

I-Product Description & Classification							
I/1	Designation	Haemostatic Forceps					
I/2	General Description	Haemostatic forceps, 14 cm					
I/3	GMDN N°	35081					
I/4	Reference Number	8001922					
I/5	Class	□ I □ Is □ Ila					
		According to Directive 93/42/EEC - Annex IX, Rules 6					
I/6	Notify Body	CE ₁₆₃₉					
I/7	Composition Raw Material	Stainless Steel 410					
I/8	Sterile						
		If, yes					
		☐ ETO ☐ Gamma ☐ Steam					
I/9	First Packaging	Number of pieces in Packaging: 1 piece per peel pack					
1/10	Picture	IM1240 25/101 Pince Hémostatique 14cm					

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	n/a			
	medical devices (in the set)				
III/2	Device contents animal	No			
	substances				
III/3	Device contents medicinal	No			
	substances				
III/4	Device comes into contact	No			
	with substances				
III/5	Used with Accessories	No			
III/6	Used in combination with	No			
	other Medical Device				







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IV- MANUFACTURING									
IV/1	Manufacturing Operations	 □ peel pack □ pouches □ boxes □ cartons □ cleaning □ sterilization 		1 pieces per peel pack 25 peel pack per box 4 boxes 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		Example of a label Pince hémostatique 1 Pince hémostatique 14-14.5cm 25 Peelpacks/carton 4 Cartons/carton Pean Klemme 14cm, steril 1 Stk/Peelpack 25 Peelpacks/Schachtel 4 Cartons/carton LOT 20.11.25 Distributor: Kuhn und Bieri AG- 3098 Köniz - www.kuhnbieri.ch Applimed SA LoT 20.11.25 CH-1618 Châtel-St-Denis						
IV/3	Place of sterilisation:	ETO gas sterilization accorde Suisse Romande)	ording to ISO 11	135-1, By CSSR (Centre de sterilisation					