

APPLIMED SA

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

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PRODUCT DATA

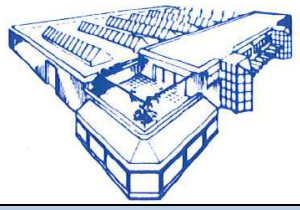
I-Product Description & Classification		
I/1	Designation	Urology Sets
I/2	General Description	Set : Urinary catheterization
I/3	GMDN N°	40247
I/4	Reference Number	4908814
I/5	Class	☐ I ☐ Is ☒ IIa According to Directive 93/42/EEC - Annex IX, Rules 5 and 6
I/6	Notify Body	**CE**1639
I/7	Composition Raw Material	1 Kidney Bowl 1 Container 125ml 6 Woven Gauze Balls Ø2.5-3cm 1 Tweezer 13cm, blue 1 Drape perforated pre-cut 60x60cm 3 Latex Gloves, Size L Wrapped in : 1 Drape 60x60cm
I/8	Sterile	☒ Yes ☐ No If, yes ☒ ETO ☐ Gamma ☐ Steam
I/9	First Packaging	Number of pieces in Packaging: 12 sets per carton
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	Set that contains all the various instruments to use for the vasectomy Examination or Urology Examination. Alone, single use and transient use (<60min)
II/2	User:	Medical staff and Professional
II/3	Contraindication of use	No recognized contraindication
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	YES
III/2	Device contents animal substances	NO
III/3	Device contents medicinal substances	NON
III/4	Device comes into contact with substances	YES
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	12 sets per cartons
IV/2	<u>Labelling: According to Directive 93/42/EEC Annex I § 13.3 and ISO 15223-1</u> • 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 1639	Example of a label	
IV/3	Place of sterilisation:	ETO gas sterilization according to ISO 11135, By CSSR (Centre de sterilisation de Suisse Romande)	

