

APPLIMED SA

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

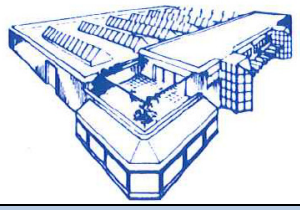
I-Product Description & Classification			
I/1	Designation	Nasal Speculum	
I/2	General Description	Nasal Speculum (killian), 35 mm	
I/3	GMDN N°	35350	
I/4	Reference Number	8001623	
I/5	Class	☐ I ☒ Is ☐ IIa According to Directive 93/42/EEC - Annex IX, Rules 5	
I/6	Notify Body	**CE**1639	
I/7	Composition 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:	Nasal Examination 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 20 peel packs 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)	