

## Ningbo Albert Novosino,Co.,Ltd

Add : No.1 Xinheng 3 Road, Cicheng Town, Jiangbei District, 315016, Ningbo,Zhejiang,China

### Technical datasheet - Medical Device

Informations as of : 2023-5-11

Completed by : Mianren Hu



Administrative informations				
Manufacturer name	Ningbo Albert Novosino Co.,Ltd			
Full address	No.1 Xinheng 3 Road Cicheng Town,Jiangbei District, 315036,Ningbo,Zhejiang,China	Phone	86-574-87527883	
		Fax	86-574-87527880	
		e-mail	748231615@qq.com	
		Website	www.albertnovosino.com	
		SRN	CN-MF-000008571	
Name of the EU representative	Humiss International B.V.			
Full address	Joop Geesinkweg 701, 1114 AB Amsterdam-Duiwendrecht, the Netherlands	Phone	+31 (0)20 369 8116	
		Fax	+31 (0) 20 369 8114	
		e-mail	business@humiss.com	
		Website	www.humiss.com	
		SRN	NL-AR-000001490	
Device informations				
Common name	Enema kit			
Commercial name	Enema kit			
Catalog reference	2L			
Basic UDI-DI	697191946EK4H			
Risk class of the MD	Class 1			
Applicable regulations	MDR			
Notified Body number (if applicable)				

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MD description	Enema kit
Technical characteristics	The tube Made from medical grade PVC material, barrel made from PP material, 2 plastic cannulas made from PE material, Plastic switch made from POM material.
Packaging/Wrapping	1pc/bag, 24bags/ctn
Composition of the device	Enema kit
Reusable (Yes/No)	No
Cleaning and disinfection method <i>(if reusable)</i>	
Min/Max temperature supported	N/A
Net weight (g)	2L plastic barrel : 168g+/-5g, The tube :80g+/-10g
Dimensions LxWxH (mm)	Plastic barrel : (185x 140 x 192)+/-5mm
Accessories	1pc 125cm tube+3pcs connectors
Area of use	Use in hospital
Indication for use	Cleaning before inspecting the rectum,sigmoid colon.
Sterilization process <i>(if MD provided sterile)</i>	
Expiry <i>(if applicable)</i>	
Destruction method	N/A
Storage conditions <i>(if applicable)</i>	
Storage temperature <i>(if applicable)</i>	
Chemical incompatibility	N/A
Contraindications	N/A
Target population	N/A
Other informations	N/A