



Medical Devices (Pvt) Ltd.
Wazirabad Road, Ugoki, Sialkot - Pakistan.

Ref: MD-DOC-00-017
Date: April 15, 2023

EU Declaration of Conformity

Medical Devices (Pvt) Ltd
Wazirabad Road, Ugoki
Sialkot, Pakistan.
Tel. +92 52 3571214 & 15
email: info@mdevices.com

Single Registration Number: **PK-MF-000021845**

Proctology Instruments

We hereby declare, under our sole responsibility, that the below mentioned devices conform to the General Safety and Performance Requirements (Annex I) in accordance with Medical Device Regulation (EU) 2017/745.

Intended Use:

Proctology instruments are handheld devices used to view the lining of the anus, rectum, and most of the sigmoid colon. These instruments with their respective accessories are used for the examination and treatment of abnormalities in the anal region of human beings.

Article Description	Trade Name	Catalogue/Reference No.	Basic UDI-DI	GMDN/EMDN
Sigmoidoscope with Distal Annular F/O Illumination, 21 x 300mm, Complete with Obturator and Lens, Satin, S.S.	-	819-090-21	8964002409 FPAS819 JV	15058/ Z 120 206 02
Sigmoidoscope with Distal Annular F/O Illumination, 21 x 250mm, Complete with Obturator and Lens, Satin, S.S.	-	819-092-21		
Sigmoidoscope with Distal Annular F/O Illumination, 21 x 200mm, Complete with Obturator and Lens, Satin, S.S.	-	819-094-21		
Sigmoidoscope with Distal Annular F/O Illumination, 16 x 250mm, Complete with Obturator and Lens, Satin, S.S.	-	819-096-16		
Sigmoidoscope with Distal Annular F/O Illumination, 12 x 200mm, Complete with Obturator and Lens, Satin, S.S.	-	819-098-12		
Lloyd Davies Sigmoidoscope set + Child Proctoscope + F/O Chamber, Satin, S.S.	Lloyd Davies	819-540-00		15058/ Z 120 206 02 35255/ G 020 603 02
F/O Anoscope with Annular Illumination, 70 x 15mm, Complete w/Obturator, Satin, S.S.	-	819-080-15		10156/ G 020 603 01



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F/O Anoscope with Annular Illumination, 70 x 20mm, Complete w/Obturator, Satin, S.S.	-	819-082-20	8964002409 FPAS819 JV	10156/ G 020 603 01
F/O Anoscope with Annular Illumination, 70 x 25mm, Complete w/Obturator, Satin, S.S.	-	819-084-25		
Beta VIII Anoscope Kit in Case, S.S	Beta VIII	819-524-00		35255/ G 020 603 02
Illumination head Disposable Proctoscope with Annular F/O Illumination Complete with Swivel Lens, Satin, S.S.	-	819-103-01		
Proctoscope with Distal Annular F/O Illumination, 130 x 21mm, Complete with Obturator and Lens, Satin, S.S.	-	819-088-30		
Accessories for Proctology Instruments				L031301
Sponge Holder Forceps, With Spring Handle, Satin, S.S. 400 mm	-	819-610-40		
Twin Bellow Insufflator.	-	819-630-00		
Shaft only with 3.5 x 8.0mm Cup Jaws, Straight, Satin, S.S. 420 mm	-	819-600-01		
Shaft only with 4.0mm Cutting Jaws, Straight, Satin, S.S. 420 mm	-	819-610-01		
Handle Only for detachable rectal Biopsy Forceps, Satin, S.S.	-	819-600-00		
Suction Tube for Sigmoidoscope, Satin, S.S. 400 mm	-	819-620-40		
Angled Clamp For F/O Light Connector, S.S. With Storz Adaptor	-	822-001-01		
Mark III Lamp Handle with 6.0 V bulb and Plug-in Transformer.	-	808-025-60		
MARK III Add-on F/O Handle S.S.		808-011-00		
Flyer Handle for "AA" size Batteries with Storz Connector, Satin, S.S.	-	819-138-01		
Flyer Handle with 2W LED, Satin, S.S.	-	819-139-20		



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It is further declared that the above Medical Devices are of Class I, by Rule 5 & 13 according to the Risk Classification of Annex VIII.



Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, ISO 10993-5: 2009, ISO 10993-10:2010, ISO 15223-1:2021, ISO 780:2015, IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 62366-1:2015, IEC 60601-1-6, RoHS II Directive 2011/65/EU and RoHS III Directive 2015/863/EU.

EU Authorized Representative:

Obelis s.a.

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B-1030 Brussels, Belgium

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SRN:BE-AR-000000106

This Declaration of Conformity is valid until a revised Declaration of Conformity is issued.

SIALKOT- PAKISTAN

Place (City & Country)

Qasim Raza, QA MANAGER

Position of Authorized Person



Signature