



HEALTHCARE
Medical Devices (Pvt) Ltd.
Wazirabad Road - 51050, Ugoki, Sialkot - Pakistan.

Ref: MD-DOC-01-010G
Date: March 22, 2025

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**

FIBER OPTIC CABLES AND ADOPTERS

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:

Fiber Optic Cable is an accessory of a medical device intended to be used for the transmission of light from the light source end to the projector end for examination.

Article Description	Gima Ref No.	MD Ref No.	Basic UDI-DI	EMDN
Fiber Optic Cable 3.5 x 1800mm	30817	830-301-18	8964002407 FOCC830 E4	V9099
Fiber Optic Cable 4.8 x 1800mm	30818	830-326-18		
Fiber Optic Cable 3.5 x 2300mm	30822	830-302-23		
Fiber Optic Cable 4.8 x 2300mm	30823	830-327-23		
Fiber Optic Cable 4.8 x 3000mm	30826	830-340-30		
Adapter for Storz Cable / Gima Light source	30810	07-0541-0036-01		
Adapter for Wolf Cable/ Gima Light source	30811	07-0541-0037-01		
Adapter for Olympus Cable / Gima Light source	30812	07-0541-0038-01		
Adapter for Pentax Cable-Gima	30815	07-0541-0040-01		
Adapter for Fujino Cable / Gima Light source	30816	07-0541-0039-01		
Adapter for LUT Cable / Gima Light source	30830	830-010-01		
Adapter for LUT Cable / STORZ Light Source	30831	830-003-01		
Adapter for LUT Cable / Wolf Light Source	30832	830-002-01		
Adapter for LUT Cable/OLYMPUS Light Source	30833	830-004-01		



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Adapter for Gima Cable / ACMI Light Source	30834	830-001-01	8964002407 FOCC830 E4	V9099
Adaptor for LUT Cable-FUJINON	30836	830-005-01		
Adaptor for Gima Cable / Pentax Light Source	30837	830-006-01		
Adapter for Gima Cable / STORZ Endoscope	30840	830-003-02		
Adapter for LUT Cable / WOLF End	30841	830-002-02		
Adapter for Gima cable / ACMI Endoscope	30842	830-001-02		
Screw-on adapter for STORZ Light	30844	830-003-03		
Screw-on adapter for WOLF Light	30845	830-002-04		

The Conformity Assessment Procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

It is further declared that the above Medical Device accessories are of Class I, by Rule 1 according to the Risk Classification of Annex VIII.



Applied Standards

ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2021.

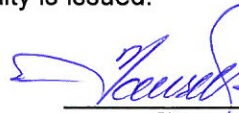
EU Authorized Representative:

Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Ph# 32.2.732.59.54
SRN:BE-AR-000000106

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

SIALKOT- PAKISTAN
Place (City & Country)

Tauseef Ajmal, Manger RA
Position of Authorized Person


Signature

