



Medical Devices (Pvt) Ltd.

Wazirabad Road, Ugoki, Sialkot - Pakistan.

Ref: MD/QA/21-038

Date: May 01, 2021

TO WHOM IT MAY CONCERN

We hereby declare that the Fiber Optic Light Cables, Connectors and Adaptors listed hereunder do not fall in the category of Medical Devices, according to the classification guidelines provided in new Medical Device Regulation MDR 2017/745.

		ADATTATORI ENDOSCOPIA E CAVI
30810	AD-0025	Connector for cable- Storz- source Gima
30811	AD-0026	Connector for cable - Wolf- source Gima
30812	AD-0027	Connector for cable - Olympus- source Gima
30815	AD-0067	Connector for cable - Pentax- source Gima
30816	AD-0028	Connector for cable - Fujinon- source Gima
30817	830-301-18	F.O. cable Ø3,5mmx1,8m (w/o adaptor)
30818	830-326-18	F.O. cable Ø4,8mmx1,8m (w/o adaptor)
30822	830-302-23	F.O. cable Ø3,5mmx2,3m (w/o adaptor)
30823	830-327-23	F.O. cable Ø4.8mmx2,3m (w/o adaptor)
30826	830-340-30	F.O. cable Ø4,8mmx3,0m (w/o adaptor)
30830	830-010-01	Adaptor cable Gima/Lut-source Gima
30831	830-003-01	Adaptor cable Gima/Lut-source Storz
30832	830-002-01	Adaptor cable Gima/Lut-source Wolf
30833	830-004-01	Adaptor cable Gima/Lut-source Olympus
30834	830-001-01	Adaptor cable Gima/Lut-source Acmi
30835	830-007-01	Adaptor cable Gima/Lut-source Heine
30836	830-005-01	Adaptor cable Gima/Lut-source Fujinon
30837	830-006-01	Adaptor cable Gima/Lut-source Pentax
30840	830-003-02	Terminal cable Gima/Lut-Endosc.Storz/Lut
30841	830-002-02	Terminal cable Gima/Lut-Endosc.Wolf
30842	830-001-02	Terminal cable Gima/Lut-Endosc.Acmi
30844	830-003-03	Connection part for Storz cable
30845	830-002-04	Connection part for Wolf cable

These items are used as component, so we hereby classify Fiber Optic Light Cables, Connectors and Adaptors as Non-Medical Device considering it's intended Use.

For and on behalf of
Medical Devices (Pvt) Ltd.

Quality Manager

