

«UKRAINIAN SCIENTIFIC INSTITUTE OF CERTIFICATION»
LIMITED LIABILITY COMPANY
04053, Ukraine, Kyiv, 7 Kudryavsky descent, office 320
UA.TR.116



CERTIFICATE OF CONFORMITY

The procedure for ensuring performance of comprehensive quality control integrated system (Annex 3 to the Technical Regulation on Medical Devices, approved by Resolution of Cabinet of Ministers of Ukraine No. 753 dated 02.10.2013 (TR)

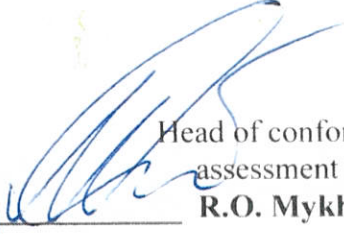
Manufacturer: Med Fibers, Inc.
Legal address: 7404 W. Detroit Street, Suite 140, Chandler, AZ 85226, USA
Manufacturing sites: Med Fibers, Inc.
7404 W. Detroit Street, Suite 140, Chandler, AZ 85226, USA
Authorized representative: LLC 'Diagnostic Center 'Medilux-Plus'
21006, Vinnytsia region, Vinnytsia, Mykola Amosova street, 6, room 1, Ukraine
Products: Surgical Laser Fibers

Conformity Assessment Body Limited Liability Company "Ukrainian Scientific Institute of Certification" (identification number UA.TR.116) confirmed that aforementioned manufacturer has implemented a quality management system for processes of development, manufacture and final inspection of mentioned devices in accordance with paragraphs 3-7 Annex 3 TR and which is subject to periodical supervision audits based on paragraphs 12-15 Annex 3 TR. For product sale of III risk class, an additional design examination certificate must be available in accordance with paragraphs 8-11 Annex 3 TR.

Basis for issuing:
Report № PR.613/6-18 dated 27.06.2018;
Decision as to certificate issuance № PR.613/7-18 dated 24.07.2018.

Certificate № **PR.543-18**
Valid until July 23th, 2023.
Version № 1. Certified since 24.07.2018.
Registration date: July 24th, 2018.




Head of conformity assessment body
R.O. Mykhalko

