



CERTIFICATE



Management system as per EN ISO 13485:2016

In accordance with TÜV AUSTRIA procedures, it is hereby certified that

FOTEK

Malisheva str., 145a,
620078, Ekaterinburg, Russian Federation

Production sites:

Malisheva str., 145e, Ekaterinburg, Russian Federation
Malisheva str., 145n, Ekaterinburg, Russian Federation

applies a management system in line with the above standard for the following scope

Design and development, manufacture, distribution and service of medical devices and related accessories for high-frequency (radiofrequency) surgery and ultrasonic cavitation surgery, devices for endosurgical systems (aspirators-irrigators, insufflators), smoke evacuation units, trolleys for placing medical devices.

Certificate Registration No. 20105223015336

Valid until 2028-11-20
Initial certification: 2022-11-21

Certification Body
at TÜV AUSTRIA GMBH

Vienna, 2025-10-06

This certification was conducted in accordance with TÜV AUSTRIA auditing and certification procedures and is subject to regular surveillance audits.

TÜV AUSTRIA GMBH Deutschstraße 10 A-1230 Wien www.tuv.at



Online Verification



www.tuv.at/certcheck