DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
14963-2019-CE-CZS-NA Rev. 0.0	PRJC-592858-2018-PRC-CZE	27 May 2024

This is to certify that the quality system of:

FOTEK OOO

Malisheva Street 145 A, liter A,620049 Ekaterinburg, Russian Federation

For design, production and final product inspection/testing of:

ACTIVE SURGICAL DEVICES AS HIGH FREQUENCY SURGICAL DEVICES, ULTRASONIC CAVITATIONAL DEVICES, MONOPOLAR INSTRUMENTS AND BIPOLAR INSTRUMENTS.

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 03 July 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

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The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	**Original certificate**	**03-07-2020**

Products covered by this Certificate:

Product Description	Product Name	Class
Active surgical devices	Bipolar instruments (electrodes) and accessories for RF-surgery, this certificate refers to the full list of devices Rev.1 dated 18.03.2020. Monopolar instruments (electrodes) and accessories for RF-surgery, this certificate refers to the full list of devices Rev.1 dated 18.03.2020 Electric surgery high frequency device «FOTEK» with accessories, models E81M, E352M, E353M, E354M, EA141M, EA142M, ONYX, ONYX-A Ultrasonic surgery cavitational device «FOTEK» with accessories, models ACTITON and ACTITON-A	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
FOTEK OOO	Malisheva Street 145 A, liter A,620049 Ekaterinburg, Russian Federation

EC Representative: OBELIS S.A, Bd. Général Wahis, 52, 1030, Brussels, Belgium

Certificate No.:
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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate