

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 615830

Issued To:

**AO NPF «BIOSS»
Sosnovaya Alleya 6a, building 1
124489 Moscow, Zelenograd
Russian Federation**

In respect of:

Design, development and manufacture of ultrasound devices, ultrasound probes, photoplethysmography sensors and sterile proctoscopes.

Проектирование, разработка и производство ультразвуковых аппаратов, ультразвуковых датчиков, фотоплетизмографических датчиков и стерильных проктоскопов.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 June 2016**

Date: **27 June 2016**

Expiry Date: **27 August 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

AO NPF «BIOSS»

Sosnovaya Alleya 6a, building 1
124489 Moscow, Zelenograd
Russian Federation

Holds Certificate Number:

MD 615829

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Development, manufacture, service and distribution of ultrasound devices and accessories.

Разработка, производство, сервисное обслуживание и продажа ультразвуковых аппаратов и аксессуаров.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-23

Latest Revision Date: 2017-08-28

Effective Date: 2017-08-28

Expiry Date: 2020-08-27

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