By Royal Charter

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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