

# EC Certificate - Product Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex VI

**No.** CE 574220  
**Issued To:** **ООО "Spinor"**  
**K. Marx Street 48/1, Office 300**  
**634009 Tomsk**  
**Russian Federation**

In respect of:

**Final inspection and test of Extremely High Frequency (EHF) and Infrared (IR) therapy devices with changeable oscillators.**

**Выходной контроль и испытания медицинских изделий для крайневысокочастотной (КВЧ) и световой инфракрасной (ИК) терапии со сменными излучателями.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex VI. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb products, an Annex III 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: **14 June 2016**

Date: **14 June 2016**

Expiry Date: **17 July 2018**

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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.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Subcontractor:**

**Service(s) supplied**

biomedoscillations UG  
(haftungsbeschränkt)  
Brunhildstrasse 60  
14513 Teltow  
Germany

**EU Representative**

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# EC Certificate - Product Quality Assurance Certificate History

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 Date: **14 June 2016**  
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Date	Reference Number	Action
14 June 2016	8483965	First issue. Transfer from another Notified Body.

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