By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 670385**

Issued To: **PERISO SA**
Varena, 4
Isone (TI),
CH-6810
Switzerland

In respect of:

Design and manufacture of magnetotherapy and low power diathermy devices for pain and inflammation reduction, bone and soft tissue healing acceleration in orthopaedics and traumatology.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2018-07-19** Date: **2018-07-19** Expiry Date: **2023-07-18**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 670385**

Date: **2018-07-19**

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Date	Reference Number	Action
Current	8707230	First issue

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05 September 2018

To whom it may concern:

I can confirm that the British Standards Institution (BSI) has issued EC certificate CE 670385 to Periso SA, in accordance with Annex II, Section 3.2 of the Medical Devices Directive 93/42/EEC. BSI is a Notified Body for the above Directive (Notified Body Number 0086).

The scope of the certificate is:

"Design and manufacture of magnetotherapy and low power diathermy devices for pain and inflammation reduction, bone and soft tissue healing acceleration in orthopaedics and traumatology".

The devices certified use high intensity and low frequencies magnetic fields.

The certificates are maintained by BSI performing regular audits of the manufacturer's quality management system.

The products listed below, which the manufacturer has declared have been manufactured under this quality system, fall within the scope of the certificates mentioned above and their technical files are reviewed by BSI on a sampling basis.

Model	Classification
CTU MEGA 20	IIa
CTU Mega 18	IIa
CTU Shock Wave (CTU S-Wave)	IIa

Each medical device has been classified by the manufacturer according to Annex IX of the Medical Devices Directive 93/42/EEC.

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In accordance with the Medical Devices Directive 93/42/EEC, a manufacturer who fulfils the obligations imposed by Annex II is permitted to apply CE marking to a device that falls within the scope of the above mentioned certificate.

Prior to placing the product on the market with CE marking the manufacturer is required to make a written declaration of conformity with the above requirements for a particular product. Such products with CE marking are then permitted to be placed on the market in the EU. It has been confirmed that the above listed product is marketed in the EU.

Yours faithfully,

Luca Roganti

Scheme Manager/ Product Specialist

BSI Medical Devices

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