

EC Certificate - Production Quality Assurance

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

No. CE 720664
Issued To: Tenscare Ltd
PainAway House
9 Blenheim Road
Epsom
Surrey
KT19 9BE
United Kingdom

In respect of:

Annex V.3: Manufacture of TENS (Transcutaneous Electrical Nerve Stimulators), EMS (Electrical Muscle Stimulators) and related non-sterile accessories.

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-10-02**

Date: **2020-11-13**

Expiry Date: **2021-12-07**

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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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Supplementary Information to CE 720664

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NBOG Code	Device Description	Intended purpose per IFU
Class IIa		
MD 1103	Transcutaneous electrical nerve stimulation (TENS) devices	N/A
MD 1103	Electrical Muscle Stimulation (EMS) devices	N/A
MD 1103	Probes	N/A

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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

Advena Ltd.
Tower Business Centre,
2nd floor, Tower Street
Swatar
BKR 4013
Malta

EU Representative

Easymed Instruments Co., Ltd
3/F, 5/F-6/F, Block A, Gupo Gongmao
Building, Fengxiang Road, Fengxiang
Industrial District, Daliang,
Shunde, Foshan, Guangdong
528300
China

Manufacture

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 720664**
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Date	Reference Number	Action
02 October 2020	3099764	First issue. Transfer from another notified body.
Current	3324460	Addition of EU representative.

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