By Royal Charter

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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Supplementary Information to CE 720664

Issued To:

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PainAway House
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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

First Issued: **2020-10-02** Date: **2020-11-13** Expiry Date: **2021-12-07**

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List of Significant Subcontractors

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

Certificate No:	**CE 720664**
Date:	**2020-11-13**
Issued To:	**Tenscare Ltd** **PainAway House** **9 Blenheim Road** **Epsom** **Surrey** **KT19 9BE** **United Kingdom**

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**

Date: **2020-11-13**

Issued To: **Tenscare Ltd**
PainAway House
9 Blenheim Road
Epsom
Surrey
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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.