

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 745087 R000

Manufacturer: TensCare Ltd

Address:

9 Blenheim Road
Epsom
Surrey
KT19 9BE
United Kingdom

Single Registration Number: GB-MF-000004156

EU Authorised Representative: Advena Limited

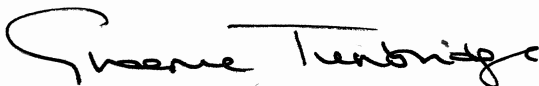
Address:

Tower Business Centre
2nd Floor, Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-12-07**

Current Issue Date: **2024-03-08**

Starting Validity Date: **2024-03-08**

Expiry Date: **2026-12-06**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Transcutaneous electrical nerve stimulation (TENS) devices	Class IIa
Electrical Muscle Stimulation (EMS) devices	Class IIa
Urogenital pelvic floor rehabilitation devices	Class IIa
Electrode probes	Class IIa



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-07	3391846	Issued
Current	30104751	Amended - Addition of subcontractor. Removal of subcontractor page.



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TensCare MDR Certificate (DOC-574) Ver. 1

Approved By:

Saskia Eldridge-Hinners - Author

July 29, 2024 9:38 AM BST

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Version History:

Author	Effective Date	Ver.	Status
Saskia Eldridge-Hinners	July 29, 2024 9:38 AM BST	1	Published
Saskia Eldridge-Hinners	May 1, 2024 8:15 AM BST	0	Superseded