

Medical Device Full Quality Assurance System Certificate  
GB22/00000417

The management system of

## EMS Physio Ltd

Greig House Annickbank Innovation Campus Annick Road Irvine KA11 4LF United Kingdom

has been assessed and certified as meeting the requirements of  
**Part II of The Medical Devices Regulations 2002, Annex II excluding  
section 4 [as modified by Part 2 of Schedule 2A to The Medical  
Devices Regulations 2002]**

For the following products  
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 03 September 2025 until 13 September 2027 and remains valid subject to satisfactory  
surveillance audits.

Issue 3. Certified since 23 November 1995



Authorised by  
Lynn Henderson

SGS United Kingdom Ltd Approved Body 0120  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



**Part II of The Medical Devices Regulations 2002, Annex II  
excluding section 4 [as modified by Part 2 of Schedule  
2A to The Medical Devices Regulations 2002]**

Issue 3

Varitherm wax bath LNC884 Paraffin wax heater – heat therapy for the treatment of arthritic conditions, soft tissue injuries and pain relief.

Megapulse Senior EMS265 Shortwave diathermy - pulsed & continuous, for the treatment of traumatic and inflammatory conditions and pain relief.

Primo Therasonic EMS3601 Therapeutic ultrasound for the treatment of traumatic and inflammatory conditions and pain relief.

Primo Therasonic EMS460 Therapeutic ultrasound for the treatment of traumatic and inflammatory conditions and pain relief.

Primo Interferential EMS960 Electrical stimulation for muscle rehabilitation and pain relief.

Primo Multidyne EMS970 Electrical stimulation for muscle rehabilitation and pain relief.

Primo Combination EMS860 Combination therapy - Ultrasound and electrical stimulation for the treatment of traumatic and inflammatory conditions, muscle rehabilitation and pain relief.

Primo EMS 560 Radial shockwave therapy for the reduction of musculoskeletal pain and improved function

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/05069

Previous certificate number: N/A

Change in between this certificate and previous one: Address change.

