

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10280-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-14333-2007-PRC-RGC

Valid Until:
27 May 2024

This is to certify that the quality system of:

Durtech System Corp.

3F., No. 27, Lane 381, Fude 1st Rd., Xizhi District, New Taipei City 22149, Taiwan.

For design, production and final product inspection/testing of:

PHYSICAL MEDICAL DEVICES

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 15 November 2019



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Tone Kolpus
Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
10280-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-14333-2007-PRC-RGC

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Revision	Description	Issue Date
0.0	Replace the certificate 72978-2010-CE-RGC-NA ver 1.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued	2017-10-16
1.0	Re-Certification	2019-11-15

Certificate history:

Product Description	Product Name	Class
Physical Medical Devices	Iontophoresis Device - DE20 TENS & EMS - DE51 - DT-1200	IIa

Products covered by this Certificate:

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Durtech System Corp.	3F., No. 27, Lane 381, Fude 1st Rd., Xizhi District, New Taipei City 22149, Taiwan.

EU Representative

AAM GmbH, Wolfsmatten 1, Bau 160, 77955 Ettenheim, Germany

Certificate No.:
10280-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:
PRJC-14333-2007-PRC-RGC

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate