DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10508-2017-CE-RGC-NA-PS Rev. 3.0	PRJC-258182-2010-PRC-TWN	27 May 2024

This is to certify that the quality system of:

Charder Electronic Co., Ltd.

No. 103, Guozhong Rd., Dali Dist., Taichung City, Taiwan (R.O.C.)

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

BODY COMPOSITION ANALYZER, MEDICAL SCALE & HEIGHT MEASUREMENT

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, 22 February 2021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

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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 .

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.

Certificate history:

Revision	Description	Issue Date
Error! Reference source not found.	Replace the certificate 85277-2010-CE-RGC-NA Rev. 5.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-07-27
1.0	Extension in scope - new products (in bold) added	2018-08-06
2.0	Change EU representative	2019-06-13
3.0	Recertification and extension in scope-new products (in bold) added Remove following devices from certificate 10508-2017-CE-RGC-NA-PS Rev.2.0: MBF6000M, MBF6010M, FFP-331, FEG-113, FEG-123, FEP-103, FFP-329, FLG-341, FLG-351, FEG-115, MS21NEO, MS2320, MS2501, MS3800, MS4610, MS4940, MS5710, MS5730, MS4400, MHS2500, MHS2600, MHS2510, MHS2610, MS4201 Change the Production Description "Body Fat Monitor" into "Body Composition Analyzer" and change its class from Im to IIa.	2021-02-22

Products covered by this Certificate:

Product Description	Product	Class
Body Composition Analyzer	MBF-6000, MBF-6010, **MA601, MA801**	**IIa**
Medical Scale	MS6000, MS7800, M-999, MS5440, MS5461, M-200, M-230, **M-250**, MS21NEOV, MS2400, MS4200, MS4400I, MS5900, M-400, M-400BT, M-410, M-410BT, **MS3510**, MHS2500I, MHS2510I, M-600, M-605, **MHS2700, MHS2710**, MS2504, MS3910, MS4202L, MS4900, MS4910, MS4971, MS5751, MS6110, M-550, M-510, M-545, M-420, M-420BT, M-430, M-430BT, M-110, M-125, MS3830, M-650, M-610, MS5410, MS5810, MS5811, MHS2600I, MHS2610I, **MS3400-1, MS3200,** MS3500, MS6111, MS2350, MS4640, MS6001, MS4970, MS5460, MS5750, MS3450	Im
Height Measurement	HM-80P, HM-80M, HM-200PW, HM-200P HM110M, HM101M, HM201M, HM230M, HM202P	Im

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The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Charder Electronic Co., Ltd.	No. 103, Guozhong Rd., Dali Dist., Taichung City 412, Taiwan (R.O.C.)

EU Representative
Obelis s.a.,Bd Général Wahis 53, B-1030 Brussels, Belgium

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