CHARDER ELECTRONIC CO., LTD.
NO.103, Guozhong Rd., Dali Dist.,
Taichung City 412, Taiwan (R.O.C.)
TEL:886-4-2406-3766 FAX:886-4-2406-5612

EU Declaration of Conformity

For the following equipment:

Stand-on Floor Scale

(Product Name)

471984638211HP

(Basic UDI)

MS2504, MS3200, MS2580, MS3400-1, MS3450, MS3910, MS3980, MS4202L, MS4203, MS4640, MS4900, MS4910, MS4970, MS4971, MS4980, MS5750, MS5751, MS6110, MS6111, M-110, M-125, M-420, M-420BT, M-430, M-430BT, M-510, M-545, M-550

(Model)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Regulation 2017/745** with the compliance the General safety and performance requirements – Annex I and the conformity assessment **Annex IX**, (Chapter I & III) which have been certified by DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway (notify body number – 2460). The Certificate No. is C538821 issued on 27 January 2025, and valid until 27 January 2030 .

For the evaluation regarding the **Class Im, Rule 13 classified in accordance with Annex VIII of MDR (EU) 2017/745,** product safety aspects, the following **harmonized standards** are applied:

-ISO 14971:2019 Medical devices - Application of risk management to medical devices;

-ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;

-EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements (ISO 15223-1:2021)

- IEC 62304:2006+AMD1:2015 Medical device software - Software life-cycle processes;

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

- IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62366-1:2015/AMD1:2020 Medical devices - Application of usability engineering to medical devices

-**EN ISO 20417:2021** Medical devices – Information to be supplied by the manufacturer

-(*)**EN45501:2015** Metrological aspects of non-automatic weighing instruments

-(**)EN301489-1 V2.2.3 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio requipment and services; Part 1: Common technical requirements

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-(**)EN 301 489-17 V3.2.4 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility

-(**)EN 300 328 V2.2.2 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum

-(**)EN 62479:2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

- No Common Specifications (CS) is applied.

Remarks:
(*) Standard EN 45501:2015 is only applicable to the deivecs with Type Approval.
(**) Standards EN 301 489-1 V2.2.3, EN 301 489-17 V3.2.4, EN 300 328 V2.2.2 and EN 62479:2010 are only applicable to the deivecs with Wireless function .

The following European Authorized Representative is stated to the declaration:

Obelis s.a.
Bd Général Wahis, 53, B-1030 Brussels, Belgium
(Company Name/Address)

SRN: BE-AR-000000106

The following person is sole responsible for the compliance of declaration:

Charder Electronic Co., Ltd.
No. 103, Guozhong Rd., Dali Dist., Taichung City 41262, Taiwan (R.O.C.)
(Manufacturer Name/Address)

SRN: TW-MF-000013673

We also declare the models meet requirements of RoHS2 Directive 2011/65/EU and delegated Directive (EU) 2015/863 with the following details:

1) All the materials from our suppliers meet RoHS 2 Directive 2011/65/EU and delegated Directive (EU) 2015/863. The product manufactured does not contain the substances or in concentrations not greater than the maximum limited value which listed in the table 1.
2) The assessment route of conformity is either by evaluating the Supplier Declaration of Conformity and/or the Test Report of accredited laboratory.

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Table 1

Substance	Maximum Limit
Cadmium (Cd)	100 ppm (0.01%)
Lead (Pb)	1000 ppm (0.1%)
Mercury (Hg)	1000 ppm (0.1%)
Hexavalent Chromium (Cr^{6+})	1000 ppm (0.1%)
Poly Brominated Biphenyls (PBB)	1000 ppm (0.1%)
Poly Brominated Diphenyl ethers (PBDE)	1000 ppm (0.1%)
Bis(2-ethylhexyl) phthalate (DEHP)	1000 ppm (0.1%)
Butyl benzyl phthalate (BBP)	1000 ppm (0.1%)
Dibutyl phthalate (DBP)	1000 ppm (0.1%)
Di-isobutyl phthalate (DIBP)	1000 ppm (0.1%)

Furthermore, in addition to the RoHS directive, regarding the European REACH Substances of Very High Concern, we have assessed the articles in accordance with the Candidate List of SVHC of EC Regulation No.1907/2006 which can refer to http://echa.europa.eu/web/guest/candidate-list-table. And we hereby certify that none of the articles we provide have any SVHC substance present in concentrations greater than 0.1% weight by weight.

Lotus Lee / PRRC
(Name/Position)

(Legal Signature)

08/02/2025
(Date of Issue [dd/mm/yyyy])

Taiwan
(Place of Issue)

Document Number: MDRD1-5-0-01
The Issued Date: 08 Feb., 2025
Rev: 01