CHARDER ELECTRONIC CO., LTD.
NO.103, Guozhong Rd., Dali Dist.,
Taichung City 41262, Taiwan (R.O.C.)
TEL:886-4-2406-3766 FAX:886-4-2406-5612

EU Declaration of Conformity

For the following equipment:

Lift Scale

(Product Name)

MHS2500I, MHS2510I, MHS2600I, MHS2610I, M-600, M-605, MHS2700, MHS2710

(Model, Designation)

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 Devices Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance the Essential Requirements – Annex I and the conformity assessment **Annex II EXCLUDING SECTION 4 OF MDD** to be certified by DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (notify body number – 2460).

For the evaluation regarding the **Class Im, Rule 12,** product safety aspects, the following **harmonized standards** are applied:-

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

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

-**EN ISO 15223-1:2016** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

-**EN 62304:2006** Medical device software - Software life-cycle processes;

-**EN60601-1:2006/A1:2013** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

-**EN60601-1-2:2015** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

-**EN 60601-1-6:2010** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

-**EN 62366:2008** Medical devices - Application of usability engineering to medical devices

-**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

-**EN 301 489-17 V3.1.1** 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)

CHARDER ELECTRONIC CO., LTD.
NO.103, Guozhong Rd., Dali Dist.,
Taichung City 41262, Taiwan (R.O.C.)
TEL:886-4-2406-3766 FAX:886-4-2406-5612

The following European Authorized Representative is stated to the declaration:

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

The following person is 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)

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.

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%)

Lotus Lee / Management Rep. (Name/Position)

(Legal Signature)

21/05/2021 (Date: dd/mm/yyyy)

Document Number: MDD1-4-3-01
The Issued Date: May/21/2021
Rev: 01