

## EU Declaration of Conformity

### For the following equipment:

Body Composition Analyzer

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(Product Name)

MBF6000, MBF6010, MA601, MA801

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(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 IIa, Rule 10**, 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 equipment 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)

**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)

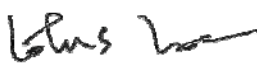
We also declare the models meet requirements of RoHS2 Directive 2011/65/EU and delegated Directive (EU) 2015/863 with the following details:

- 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 <sup>6+</sup> )	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)

  
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(Legal Signature)

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