



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

## EC Declaration of Conformity

### For the following equipment:

Height Measurement

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(Product Name)

HM80P, HM80M, HM101M, HM110M, HM200PW, HM200P, HM201M, HM202P, HM230M

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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 Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance the essential requirement – Annex I and the conformity assessment **Annex II EXCLUDING SECTION 4 OF MDD** to be certified by DNV GL Presafe AS (notify body number – 2460)

For the evaluation regarding the **Class Im, Rule 1**, product safety aspects, the following **harmonized standards** are applied:-

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

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

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

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-**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

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We also declare the models meet requirements of RoHS2 Directive 2011/65/EU with the following details:

- 1) All the materials from our suppliers meet RoHS 2 Directive 2011/65/EU. 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%)
Diisobutyl phthalate (DIBP)	1000 ppm (0.1%)

**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 412, Taiwan (R.O.C.)

(Manufacturer Name/Address)

Lotus Lee / Management Rep.

(Name/Position)



(Legal Signature)

10/08/2020

(Date: dd/mm/yyyy)