

## EU Declaration of Conformity

The Non-Automatic Weighing Instrument

III

|                                  |                             |
|----------------------------------|-----------------------------|
| Manufacturer                     | Charder Electronic Co., Ltd |
| Model                            | MS-2350                     |
| EC Type Approval Certificate No. | T7614                       |

### The Metrological Aspects of Non-Automatic Weighing Instruments

|                         |                             |
|-------------------------|-----------------------------|
| EN45501:2015 (module D) | Notified Body Number – 0122 |
| EN45501:2015 (module B) | Notified Body Number – 0122 |

The non-automatic weighing instrument corresponds to the production model described in the EC Type Approval Certificate and requirements of the following EC Directives:

|                                       |                                              |
|---------------------------------------|----------------------------------------------|
| 2014/31/EU                            | Non-Automatic Weighing Instruments Directive |
| 93/42/EEC as amended by<br>2007/47/EC | Medical Device Directive                     |
| 2014/53/EU                            | Radio Equipment Directive                    |

The applicable harmonized standards are:

|                         |                                                                                                                                                                                                                                        |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN 45501:2015           | The Metrological Aspects of Non-Automatic Weighing Machines                                                                                                                                                                            |
| EN ISO14971:2012        | Medical devices - Application of risk management to medical devices                                                                                                                                                                    |
| EN ISO10993-1:2009      | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process                                                                                                                             |
| EN 60601-1:2006/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance                                                                                                                                 |
| EN 60601-1-2:2015       | 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 62304:2006           | Medical device software - Software life-cycle processes                                                                                                                                                                                |
| EN ISO 15223-1:2021     | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements                                                                                              |
| EN 301 489-1 V1.9.2     | 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 and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems                                 |
| EN 300 328 V2.1.1       | Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU |

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Date: Mar. 02. 2022

Signature: \_\_\_\_\_

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