

EU Declaration of Conformity

The Non-Automatic Weighing Instrument

III

Manufacturer	Charder Electronic Co., Ltd
Model	MS-4400I
EC Type Approval Certificate No.	T8887

The Metrological Aspects of Non-Automatic Weighing Instruments

EN45501:2015 (module D)	Notified Body Number – 0126
EN45501:1992 (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 2007/47/EC	Medical Device Directive

The applicable harmonized standards are:

EN45501:2015	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
EN60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
EN60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN62304:2006	Medical device software - Software life-cycle processes
EN980:2008	Symbols for use in the labelling of medical devices

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

Date: August 25, 2017

Signature: _____



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