charder®

EU Declaration of Conformity

The Non-Automatic Weighing Instrument (III)

Manufacturer	Charder Electronic Co., Ltd
Model	MS5460
EC Type Approval Certificate No.	T10993

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 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/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
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
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

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

Date: Mar. 02. 2022

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