



Declaration of Conformity

We declare, under our solo responsibility, that the products:

Product Name Digital PD Meter

Model No. PD-82II

are in conformity with the EU Medical Devices Regulation (MDR), Regulation (EU) 2017/745

Classification Class I with a measuring function

(Non-invasive/active medical devices / Application rules; 13 / Class I)

Conformity assessment Annex XI part A

Basic UDI-DI 456220842PD001ZL

This declaration of conformity is based on the Regulation (EU) 2017/745.:

2017/745 — concerning medical devices, Annex IV

EU Quality Assurance Certificate JP25/00000309

Manufacturer:

Name; TOWA MEDICAL INSTRUMENTS Co., Ltd.

Address; 1698-2 Nakano, Nakano-shi, Nagano, 383-0013, Japan

SRN; JP-MF-000004196

Authorized European Representative:

Name; Rexxam Co.,Ltd. Netherlands Office

Address; Steenovenweg 5, 5708HN Helmond, The Netherlands

SRN; NL-AR-000002643

The authorized signatory to this declaration:

TOWA MEDICAL INSTRUMENTS Co.,Ltd.

17 June, 2026

Place and date of issue

Signature: _____

Name: Koichi Kasuya

Position: President

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Head office・factory

Applied Standards:

	Standard No,	Title
1	EN ISO 13485:2016 +A11:2021	Medical devices - Quality management systems – Requirement for regulatory purposes
2	EN ISO 14971:2019 +A11:2021	Medical devices – Application of risk management to medical devices
3	EN ISO 15004-1:2020	Ophthalmic instruments – Fundamental - requirements and test methods Part 1: General requirements applicable to all ophthalmic instruments
4	EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process
5	IEC 60601-1 :2005/A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
6	IEC 60601-1-2 Ed.4.0:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
7	IEC 60601-1-6:2010+AMD2:2020	Medical electrical requirement – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
8	IEC 62366-1:2015+AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices – Amendment 1
9	MEDDEV 2.7.1 rev.4	Clinical evaluation: A guide for manufacturers and Notified bodies under DIRECTIVES 93/42/EEC and 90/385/EEC
10	EN ISO 15223-1:2021	Medical devices – Symbols to be used with medica device labels, labelling and information to be supplied – Part 1: General requirements
11	ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
12	IEC 62304:2006+AMD1:2015	Medical device software – Software life-cycle processes – Amd.1
13	2011/65/EU	Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical Equipment

CS: Not applicable. This device is not specified in Annex XVI.

Notified body: SGS Belgium NV NB1639