Document No: YMA-21054(3)

EU DECLARATION OF CONFORMITY

Hereby we declare under our sole responsibility that the following product to which this declaration relates complies with the provisions of the following legislations. All supporting documents are retained under the premises of the manufacturer and the authorized representative.

Manufacturer:	Yamagata Casio CO., LTD.
	5400-1 Higashine-ko, Higashine-city, Yamagata 999-3701 Japan
Product name:	Dermatology scope
Model name:	DZ-S50
Serial number:	from 20D00501A
Accessory:	DSL-50M Conversion Lens

Regulation:	(EU) 2017/745 (Medical Device Regulation)
Classification:	Class I (in accordance with Rule 1 and 13, Chapter III of Annex VIII)
Conformity assessment:	Annex II + Annex III + Annex IV
Manufacturer's SRN	JP-MF-000022932
Authorized representative:	MedNet EC-REP GmbH (SRN:DE-AR-000000002)
	Borkstrasse 10, 48163 Münster, Germany
Basic UDI-DI:	458242978019GE

Applied standard/normative document:

EN ISO 10993-1: 2009	EN ISO 13485: 2016	EN ISO 14971: 2019
EN ISO 15223-1: 2016	EN ISO 20417: 2021	IEC 60601-1: 2005 +A1: 2012
IEC 60601-1-2: 2014	IEC 62366-1 2015 (ed. 1.0)	MEDDEV 2.7/1 rev.4
MDCG2023-3		

Technical documentation:	YMA-21015

Regulation:	(EU) 2023/1542 (Battery Regulation)
Battery model:	DNP-200M including all batches (portable battery)
Conformity assessment:	Module A (Annex VIII)
Technical documentation:	YMA-24058

Directive:	2011/65/EU (RoHS II)
Conformity assessment:	Module A (Annex II to Decision No 768/2008/EC)
Harmonised standard:	EN IEC 63000:2018
Technical documentation:	YMM-23016