Document No.: YMA-21054(4)

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

Intended purpose: Casio Dermatology scope DZ-S50 is intended to be used to observe the skin and skin lesions on the

patient's skins.

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