

EU DECLARATION OF CONFORMITY

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

Regulation: 2017/745/EU (Medical Device Regulation)

Product name: Dermatology scope

Model name: DZ-S50

Basic UDI-DI: 458242978019GE

Serial number: from 20D00501A

Accessories: Conversion lens (DSL-50M)

Risk class: Class I according to rule 13 in Ch. 3 of Annex VIII of 2017/745/EU

Conformity assessment: Annex II + Annex III + Annex IV of 2017/745/EU

Manufacturer: Yamagata Casio CO., LTD.

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EUDAMED SRN: JP-MF-000022932

European authorized representative: MedNet EC-REP GmbH

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Applied standard/normative document:

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

Technical file: refer to YMA- YMA-21015

Directive: 2011/65/EC (RoHS II)

Applied standard: EN IEC 63000:2018