

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 camera

Model name: DZ-D100

Basic UDI-DI: 458242978018GC

Serial number: from 10D00501A

Accessories: Small diameter/3D adaptor set (DAS-100M), Microscope adaptor (DMS-100M), Protective film (DFP-100M)

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

Borkstrasse 10, 48163 Münster, Germany

Applied standard/normative document:

EN ISO 10993-1: 2009	EN ISO 13485: 2016	EN ISO 14971: 2019
EN ISO 15223-1: 2016	IEC 60601-1: 2005 +A1: 2012	IEC 60601-1-2: 2014
IEC62304:2006+A1:2015	IEC 62366-1 2015 (ed. 1.0)	MEDDEV 2.7/1 rev.4

Technical file: refer to YMA-21006

Directive: 2014/53/EU (Radio Equipment Directive)

Conformity assessment procedure: INTERNAL PRODUCTION CONTROL Module A (Annex II of 2014/53/EU)

Applied standard:	EN 300 328 v2.2.2	EN 301 489-1 v2.2.3	EN 301 489-17 v3.2.4
	EN 62479: 2010	IEC 60601-1: 2005 +A1: 2012	IEC 60601-1-2: 2014

Directive: 2011/65/EC (RoHS II)

Applied standard: EN IEC 63000:2018