

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 camera		
Model name:	DZ-D100		
Intended purpose:	The Dermatology camera DZ-D100 is a camera intended to capture high quality dermoscopic images.		
Serial number:	from 10D00501A		
Accessory:	DAS-100M Small-diameter & 3D adapter set DMS-100M Microscope adapter DFP-100M Protective Film		
Regulation:	(EU) 2017/745 (Medical Device Regulation)		
Manufacturer's SRN:	JP-MF-000022932		
Authorized representative:	MedNet EC-REP GmbH (SRN:DE-AR-000000002) Borkstrasse 10, 48163 Münster, Germany		
Classification:	Class I (in accordance with Rule 1 and 13, Chapter III of Annex VIII)		
Conformity assessment:	Annex II + Annex III + Annex IV		
Basic UDI-DI:	458242978018GC		
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 62304:2006+A1:2015 IEC 62366-1 2015 (ed. 1.0) MEDDEV 2.7/1 rev.4 MDCG2023-3		
Technical documentation:	YMA-21006		
Regulation:	(EU) 2023/1542 (Battery Regulation)		
Battery model:	DNP-100M including all batches (portable battery)		
Conformity assessment:	Module A (Annex VIII)		
Technical documentation:	YMA-24057		
Directive:	2014/53/EU (Radio Equipment Directive)		
Conformity assessment:	Module A (Annex II)		
Harmonised 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		
Technical documentation:	YMA-24035		
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-23015		