

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:	COLPOCAMERA		
Intended purpose:	The COLPOCAMERA is intended to assist doctors in diagnosing abnormalities and selecting biopsy sites by magnifying and observing the tissues of the vagina, cervix and genital area. It is intended for use in hospitals, clinics, and doctors' offices.		
Model name:	DZ-C100		
Serial number:	from 30D00501A		
Accessory:	CST-100M CAMERASTAND		
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		
Basic UDI-DI:	458242978020FX		
Classification:	Class I (in accordance with Rule 1 and 13, Chapter III of Annex VIII)		
Conformity assessment:	Annex II + Annex III + Annex IV		
Applied standard/normative document:	EN ISO 10993-1: 2009 EN ISO 13485: 2016 EN ISO 14971: 2019 EN ISO 15223-1: 2021 EN ISO 20417: 2021 IEC 60601-1: 2005+A1: 2012 IEC 60601-1-2: 2014 IEC 62304: 2006+A1: 2015 IEC 62366-1: 2015+A1: 2020 MEDDEV 2.7/1 rev.4 MDCG2023-3		
Technical documentation:	YMA-22013 for DZ-C100 YMA-22014 for CST-100M		
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-23016		
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-23018		

This declaration is valid until further notice.