EU DECLARATION OF CONFORMITY

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

Regulation:	(EU) 2017/745 (Medical Device Regulation)		
Product name:	COLPOCAMERA		
Model name:	DZ-C100		
Basic UDI-DI:	458242978020FX		
Serial number:	from 30D00501A		
Accessory:	CAMERA STAND (CST-100M)		
Risk class:	Class I (in accordance with Rule 1, Chapter III of Annex VIII)		
Conformity assessment:	Annex II + Annex III + Annex IV		
Manufacturer:	Yamagata Casio CO., LTD.		
	5400-1 Higashine-ko, Higashine-shi, Yamagata 999-3701 Japan		
EUDAMED SRN:	JP-MF-000022932		
Authorized representative:	MedNet EC-REP GmbH (SRN:DE-AR-000000002)		
	Borkstrasse 10, 48163 Münster, Germany		
Applied standard/normative document:			
	EN ISO 13485: 2016	EN ISO 14971: 2019	IEC 60601-1: 2005+A1: 2012
	IEC 60601-1-2: 2014	IEC 62304: 2006+A1: 2015	IEC 62366-1: 2015+A1: 2020
	EN ISO 15223-1: 2021	EN ISO 20417: 2021	MEDDEV 2.7/1 rev.4
	MDCG2023-3		
Technical documentation:	YMA-22013 for DZ-C100/YMA-22014 for CST-100M		

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)
Harmonised standard:	EN IEC 63000:2018
Technical Documentation:	YMM-23018