

UK DECLARATION OF CONFORMITY

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

Legislation: The Medical Devices Regulations 2002
Product name: COLPOCAMERA
Model name: DZ-C100
Serial number: from 30E00501A
Accessory: CAMERA STAND (CST-100M)
Risk class: Class I (in accordance with Rule 1, Chapter III of Annex IX to 93/42/EEC)
Conformity assessment: Annex VII to 93/42/EEC
Manufacturer: Yamagata Casio CO., LTD.
5400-1 Higashine-ko, Higashine-shi, Yamagata 999-3701 Japan
UK Responsible Person: MediMap Ltd
2, The Drift, Thurston, Suffolk IP31 3RT, United Kingdom

Designated 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

Technical documentation: YMA-22013 for DZ-C100/YMA-22014 for CST-100M

Legislation: The Radio Equipment Regulations 2017
Conformity assessment: Module B and C (Schedule 3)
Approved body: UL Verification Services Inc. (Body No. 0984)
Designated 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-23017

Legislation: The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
Designated standard: EN IEC 63000:2018
Technical Documentation: YMM-23018