

Medical imaging made easy™



EU DECLARATION OF CONFORMITY

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SRN of EAR (Single Registration Number): NL-AR-000018862

Certification mark:



We, MediCapture, Inc., hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745. The device(s) is/are Class 1 following Rule 13 of Annex VIII of REGULATION (EU) 2017/745. The following conformity assessment procedure has been performed according to Annex II and III for these devices according to MDR Art 52.7.

The following Common Specifications have been used and in relation to which conformity is declared:
Not Applicable

We hereby also declare under our sole responsibility that the device(s) listed in the annex comply(ies) with the provisions of:

- ISO 13485:2016 / EN ISO 13485:2016
- EN ISO 14971:2019
- ISO 15223-1: 2021
- ISO 20417: 2021
- IEC 60601-1:2005 + A1:2012+A2:2020 (International standard) - (3.2 edition)
- EN IEC 63000:2018
- EN 60601-1:2006+A1:2013+A12:2014+ A2:2021
- EN 60601-1-2:2015 + A1:2021 (EMC)
- EN 60601-1-6:2010 + A1:2015
- EN IEC 61000-3-2:2019+A1:2021
- EN 61000-3-3:2013+A2:2021
- EN 60601-1-6:2010/A2:2021
- IEC 60601-1-6:2010 +A1:2013+A2:2020

The present declaration is in conformity with Directive (2011/65/EU (RoHS), and 2012/19/EU (WEEE)

LouAnn Fare
Director, Regulatory Affairs (PRRC for manufacturer)
Place / date: Plymouth Meeting, Pennsylvania / November 19, 2024

Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model / Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ EMDN code
1	MTR133	MTR33	Medical Touch Screen Video Recorder	This device is intended to record video and images from a variety of medical imaging systems.	1	13	0859151005MTR8D	63260
2	MTR156	MTR156	Medical Touch Screen Video Recorder	This device is intended to record video and images from a variety of medical imaging systems.	1	13	0859151005MTR8D	63260

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