

Medical imaging made easy™



EU DECLARATION OF CONFORMITY

We,
Name and address of manufacturer: *MediCapture, Inc.
2250 Hickory Road, Suite 200
Plymouth Meeting, PA 19462 – USA*

declare on our own responsibility that the medical device(s):
Model Names *MVR Pro (MVR409);
MVR (MVR420)*

The above-mentioned device(s) comply with the following Union harmonization legislation:

Radio Equipment Directive ***2014/53/EU***

The following harmonized standards have been applied:

Article 3.1a:
EN 60601-1:2006/A1:2013/A12:2014
EN IEC 62311:2020
EN 62479:2010

Article 3.1b:
ETSI EN 301 489-1 V2.2.3: 2019-11
ETSI EN 301 489-17 V3.2.4: 2020-09
EN 60601-1-2:2015 (IEC 60601-1-2:2014)

Article 3.2:
ETSI EN 300 328 V.2.2.2:2019-07
ETSI EN 301 893 V.2.1.1:2017-05

Accessories and components which allow the radio equipment to operate as intended and covered by the EU declaration of conformity: *Antenna 55P004-0005-A*

Signed for and on behalf of:

MediCapture, Inc.
Plymouth Meeting, Pennsylvania, November 11, 2021
Place, date

A handwritten signature in black ink, appearing to read "LouAnn Fare".

LouAnn Fare, Director Regulatory Affairs
Name and Function