Canon

Ref. No.: 17-M02-10

DECLARATION OF CONFORMITY

We

Manufacturer	Canon Inc.
	9-1, Imaikami-cho, Nakahara-ku, Kawasaki, Kanagawa 211-8501, Japan
Authorized representative	Canon Europa N.V. Medical Imaging Group
in Europe	Bovenkerkerweg 59, 1185 XB Amstelveen, The Netherlands

declare under our sole responsibility that product

DIGITAL RADIOGRAPHY model: CXDI-810C Wireless

(Class IIa, Rule10)

is in conformity with essential requirements of EC Directive(s)

93/42/EEC

by applying the following harmonized standards

EC Directive(s)	Reference of standard(s) and amendment(s)
93/42/EEC	EN ISO13485:2016/AC:2018
	EN 60601-1:2006/ A11:2011/ A1:2013
	EN 60601-1-2:2015
	EN 60601-1-3:2008/A11:2016
	EN 60601-1-6:2010
	EN 60601-2-54:2009
	EN 62220-1:2004
	EN 62304:2006/AC:2008
	EN 62366:2008
	EN ISO 14971:2012
	EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009,
	EN ISO 10993-10:2010, EN ISO 10993-12:2012, EN ISO 10993-18:2009
	EN ISO 15223-1:2016, EN 1041:2008

and a "Full Quality Assurance System" according to EC Directive 93/42/EEC Annex II except Section 4 by the following Notified Body as stated on the certificate of HD 1230912-1.

Notified Body:

Name	TUV Rheinland LGA Products GmbH (ID No. 0197)
Address	Tillystraße 2 90431 Nürnberg Germany

Note:

1. The CE Marking is affixed from the year '17.
2. This statement of conformity is only valid in conjunction with the release document for each serial number of produced devices.
3. The contents marked with an asterisk is that added or revised to our previous Declaration of Conformity No. 17-M02-09.
4. Copies of the rating plates of these models are attached.
5. Accessory: (Option)
   CXDI Control Software NE, Battery Pack LB-4A, Multi Box MB-4A, Docking Station DS-4A, Ready Indicator RI-3A, PC Connection Cable CP-4A, Status Indicator SI-4A, Wiring Cable WC-4A, Scatter Correction for CXDI Series, Advanced Edge Enhancement, Free Rotation for CXDI Series, *Intelligent NR

Date: November 26, 2021

Akira HIRAI
Medical Equipment Quality Assurance Div.
Medical Components Group
CANON INC.

Base Model: CXDI-810C Wireless

Ref. No.: 17-M02

RECORD OF DECLARATION OF CONFORMITY FOR MEDICAL DEVICE

Date	Contents of Technical Report		QA System ISO 13485	Essential Requirement	Comments
	Electrical Safety	EMC			
2017.05.15	Q40-1260	Q40-1261	HD 60113491 0001	May 12, 2017	Suffix No. 01 is issued. (Model CXDI-810C Wireless new registration)
2017.12.25	—	—	—	December 25, 2017	Suffix No. 02 is issued. - Update of the harmonized standard
2018.9.25	—	—	—	September 21, 2018	Suffix No. 03 is issued. - Changing Manufacturer name
2019.1.23	-	-	-	January 23, 2019	Suffix No. 04 is issued. - Adding option Advanced Edge Enhancement
2019.4.3	—	—	—	April 3, 2019	Suffix No. 05 is issued. - update of the harmonized standard (applicable to EN ISO13485:2016)
2019.7.18	—	—	HD 60140845 0001	—	Suffix No. 06 is issued. - Update of the EC Certificate
2019.8.6	—	—	—	August 6, 2019	Suffix No. 07 is issued. - Update of the harmonized standards
2019.12.20	—	—	—	—	Suffix No. 08 is issued. - Update of the optional function of software
2021.4.12	—	—	HD 1230912-1	March 24, 2021	Suffix No. 09s issued. - Update of the EC Certificate
2021.11.26	—	—	—	November 18, 2021	Suffix No. 10s issued. - Adding "Intelligent NR"