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KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

Name	KONICA MINOLTA, INC.
Address	1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan
Single Registration Number	JP-MF-000008214

declares, sole responsibility, that the following product

Generic Device Group:	Laser Imagers
Type:	LASER IMAGER
Model (Product Name):	DRYPRO SIGMA 2
Basic UDI-DI:	4560141920000688T
Intended Purpose:	The device is intended for use in the acquisition and process of radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures.
Classification:	Class I, Rule 1, according to Annex VIII of REGULATION (EU) 2017/745
Serial Number:	from 203525 to 999999 (A9R4) from 203535 to 999999 (A9R5)

referred to in this declaration conforms with the following EU law(s):

REGULATION (EU) 2017/745, DIRECTIVE 2014/53/EU and Directive 2011/65/EU

and conforms with the following standard(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021,
EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015,
EN 60601-1-6:2010+A1:2015, EN 60825-1:2007, EN 62366:2008+A1:2015,
EN 62304:2006 for REGULATION (EU) 2017/745,
EN 300 330 V2.1.1 for DIRCTIVE 2014/53/EU,
EN IEC 63000:2018 for Directive 2011/65/EU

and that this declaration is valid upon approval for release of each product.

EU Representative

Name Konica Minolta Business Solutions Europe GmbH
Address Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands
Single Registration Number NL-AR-000002026

Signed for and on behalf of manufacturer:

Tokyo Japan, 2024-06-14
(Place and date of issue)
YOSHINORI SATO
General Manager,
Quality Assurance Operations
Healthcare Business Headquarters
(Name, function)

DocuSigned by Yoshinori Sato
Yoshinori Sato
この文書を承認する
6 14, 2024 | 10:40:55 午前 JST
CC41882571A04791AA483438368077D5
(Signature of equivalent authorized by the manufacturer)