Document No. 05ERD V.02

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 Imager
Type:	LASER IMAGER
Model (Product Name):	DRYPRO MODEL 832
Basic UDI-DI:	45601419200000583
Intended Purpose:	A 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 0922-60939 to 0922-99999 (GNPM)
Including	Printlink5-IN

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

REGULATION (EU) 2017/745 and Directive 2011/65/EU

and conforms with the following standard(s):

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008+A1:2013,
prEN ISO 15223-1:2020, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015,
EN 60601-1-6:2010, EN 60825-1:1994+A1:2002+A2:2001, EN 62366:2008,
EN 62304:2006 for REGULATION (EU) 2017/745,
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, 2021-08-24
(Place and date of issue)
HAJIME NOZAWA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

(Signature of equivalent authorized by the manufacturer)

M.S.D.N: 0312376664 - C.T.C.P. CÔNG TY CỔ PHẦN THIẾT BỊ VẬT TƯ Y TẾ 2H QUẬN 7 - TP. HỒ CHÍ MINH

TỔNG GIÁM ĐỐC
Trần Thị Mỹ Duyên