KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

Name	KONICA MINOLTA, INC.
Address	1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

declares, sole responsibility, that the following product

GMDN term:	Diagnostic x-ray digital imaging conversion system
GMDN code:	61109
Generic Device Group:	Direct Digitizers
Type:	DIRECT DIGITIZER
Model:	SKR 4000
Classification:	Class IIa, Rule 10, 1st Paragraph, 3rd indent, 93/42/EEC
Serial Number:	From ACNN-00023 to ACNN-99999

Reference: AeroDR NS 1417 is the commercial name of SKR 4000

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

DIRECTIVE 93/42/EEC, confirmed by the procedure of its Annex II, and
Directive 2011/65/EU

and conforms with the following standard(s):

EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366:2008,
EN 62304:2006+AC:2008, EN ISO 10993-1:2009+AC:2010, EN 1041:2008,
EN ISO 15223-1:2016, EN ISO 13485:2016, EN ISO 14971:2012
for DIRECTIVE 93/42/EEC,
EN IEC 63000:2018 for Directive 2011/65/EU

and that this declaration is valid upon approval for release of each product.
The manufacturer will keep on file for review the technical documentation.

EU Representative

Name	Konica Minolta Business Solutions Europe GmbH
Address	Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands

Notified Body responsible only for implementation of the Directive 93/42/EEC

Name	TÜV Rheinland LGA Products GmbH
Address	Tillystrasse 2, 90431 Nürnberg, Germany

Signed for and on behalf of manufacturer:

Tokyo Japan, 2020-10-15
(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)

CE 0197