



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 3000
Classification: Class IIa, Rule 10, 1st Paragraph, 3rd indent, 93/42/EEC

Including components shown in other page(s) of this declaration,

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 60601-1-2:2007+AC:2010, 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 13485:2012+AC:2012, EN ISO 14971:2012
for DIRECTIVE 93/42/EEC,
EN 50581:2012 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 Hoogoorddreef 9, 1101 BA Amsterdam, 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, 2017-10-01
(Place and date of issue)
YASUSHI YAMANAKA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

(Signature of equivalent authorized by the manufacturer)

CE 0197



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Components and their Serial Numbers

| Name of Component | Serial Numbers for the Component | |
|-------------------|----------------------------------|------------|
| | from | to |
| P-61 | A8CE-00437 | A8CE-99999 |
| | A9YC-00001 | A9YC-99999 |
| G-11 | A9G4-00282 | A9G4-99999 |
| G-21 | A9G5-00584 | A9G5-99999 |
| G-22 | A9G7-00249 | A9G7-99999 |
| G-31 | A9G6-00233 | A9G6-99999 |
| G-32 | A9YM-00546 | A9YM-99999 |
| G-33 | AAH2-00001 | AAH2-99999 |

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