



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**

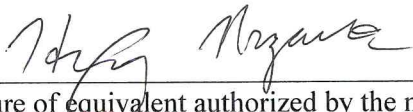
Name Konica Minolta Business Solutions Europe GmbH  
Address Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands

**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