Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

Digitally signed by Botnaru Andrei
Date: 2024.05.14 10:07:03 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Date April 11, 2024

Shimadzu Corporation, Medical Systems Division
1, Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 Japan

Notified Body Confirmation Letter
Reference. : SHIMA_CL607_2024-04-11

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Shimadzu Corporation, Medical Systems Division
1, Nishinokyo-Kuwabara-cho
Nakagyo-ku, Kyoto
604-8511 Japan
SRN Number: JP-MF-000025145

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

On behalf of the Notified Body

Michiaki Aihara
Certification body

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
X-RAY TV SYSTEM SONIALVISION G4	Class IIb	N/A	HD 60147504 0001 NB# 0197
Digital Angiography System Trinias	Class IIb	N/A	HD 60147504 0001 NB# 0197
RADspeed Pro	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.2/0.8P38C-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.3/0.8P18DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P13DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P33DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P18DE-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P38DE-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 1/2P13DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 1/2P33D-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 1/2P18DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 1/2P38D-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.3/0.8P323DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P123DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P323DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.8P323DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.2/0.8P39CK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.3/0.8P324DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P324DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P164DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P364DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P324DK-125	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P364DK-125	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.8P324DK-85	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.4/0.7JG326D-265	Class IIb	N/A	HD 60147504 0001 NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
X-ray tube assembly 0.7/1.2JG326D-265	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY HIGH VOLTAGE GENERATOR UD150B-40	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY HIGH VOLTAGE GENERATOR UD150V-40	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY HIGH VOLTAGE GENERATOR UD150L-40	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY HIGH VOLTAGE GENERATOR UD150L-40F	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY HIGH VOLTAGE GENERATOR UD150L-40E	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray radiography table BK-12HK	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray radiography table BK-120MK	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-Ray Radiography Table BK-200	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY RADIOGRAPHY STAND BR-120	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray Radiography Stand BR-120T	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY RADIOGRAPHY STAND BR-120M	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY TUBE STAND FH-20HR	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY TUBE STAND FH-21HR	Class IIb	N/A	HD 60147504 0001 NB# 0197
Ceiling Type X-ray Tube Support CH-200M	Class IIb	N/A	HD 60147504 0001 NB# 0197
CEILING TYPE X-RAY TUBE SUPPORT CH-200	Class IIb	N/A	HD 60147504 0001 NB# 0197
COLLIMATOR TYPE R-300	Class IIb	N/A	HD 60147504 0001 NB# 0197
Collimator Type R-20J	Class IIb	N/A	HD 60147504 0001 NB# 0197
Radiography System RADspeed fit	Class IIb	N/A	HD 60147504 0001 NB# 0197
GENERAL RADIOGRAPHIC SYSTEM EZy-Rad Pro	Class IIb	N/A	HD 60147504 0001 NB# 0197
Mobile X-ray System MUX-10	Class IIb	N/A	HD 60147504 0001 NB# 0197
Mobile X-ray System MobileDaRt Evolution	Class IIb	N/A	HD 60147504 0001 NB# 0197
Mobile X-ray System MobileArt Evolution	Class IIb	N/A	HD 60147504 0001 NB# 0197
FDR Visionary Suite	Class IIb	N/A	HD 60147504 0001 NB# 0197
Mobile X-ray System FDR Go	Class IIb	N/A	HD 60147504 0001 NB# 0197
Mobile X-ray System Mobirex i9	Class IIb	N/A	HD 60147504 0001 NB# 0197
SURGICAL MOBILE C-ARM IMAGING SYSTEM OPESCOPE ACTENO	Class IIb	N/A	HD 60147504 0001 NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-RAY R/F SYSTEM FLUOROspeed	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 1.2U161CS-31	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.7U161CS-36	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.7U163CS-36	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.7/1.3U163C-36	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1J327C-280	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1J317C-282	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1J317C-285	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P326D-150	Class IIb	N/A	HD 60147504 0001 NB# 0197
X-ray tube assembly 0.6/1.2P366D-150	Class IIb	N/A	HD 60147504 0001 NB# 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-11	SHIMA_CL607_2024-04-11	Initial issue