Business Stream Products
Certification Department

Digitally signed by Botnaru Andrei
Date: 2024.07.05 15:00:32 EEST
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

FUJIFILM Corporation
26-30, Nishiazabu 2-chome, Minato-ku
Tokyo 106-8620
Japan

Contact

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Date June 03, 2024

Notified Body Confirmation Letter
Reference. : FUJIF_MDR Application 2023-12-11; order #150295644

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:

Company name: FUJIFILM Corporation
Company Address: 26-30, Nishiazabu 2-chome, Minato-ku
Zip code, City: Tokyo 106-8620
Country: Japan
SRN Number: JP-MF-000010401

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. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Video Endoscope EC-760ZP-V/L	Class IIa	Video Endoscope EC-760ZP-V/L	Certificate # G1 020011 0048 rev 01 NB # 0123
Console Advance	Class IIa	Console Advance	Certificate # G1 020011 0048 rev 01 NB # 0123
Ultrasonic Processor SP-900	Class IIa	Ultrasonic Processor SP-900	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Pump JW-3	Class IIa	Water Pump JW-3	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Jet Tube JT-3RW	Class IIa	Water Jet Tube JT-3RW	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-3JW	Class IIa	Water Tank WT-3JW	Certificate # G1 020011 0048 rev 01 NB # 0123
FWU-1 FWT C5-2	Class IIa	iViz Wireless	Certificate # G1 020011 0048 rev 01 NB # 0123
FWU-1 FWT L10-5	Class IIa	iViz Wireless	Certificate # G1 020011 0048 rev 01 NB # 0123
FWU-1 TABLET DISPLAY UNIT	Class IIa	iViz Wireless	Certificate # G1 020011 0048 rev 01 NB # 0123
FWU-1 APPLICATION SOFTWARE	Class IIa	iViz Wireless	Certificate # G1 020011 0048 rev 01 NB # 0123
FCR PROFECT CS Plus	Class IIa	FCR PROFECT CS	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III C35i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III C43i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III C25i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III G35i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III G43i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-760Z-V/M	Class IIa	Video Endoscope EC-760Z-V/M	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-760P-V/L	Class IIa	Video Endoscope EC-760P-V/L	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-720R/M	Class IIa	Video Endoscope EC-720R/M	Certificate # G1 020011 0048 rev 01 NB # 0123
Processor EP-6000	Class IIa	Processor EP-6000	Certificate # G1 020011 0048 rev 01 NB # 0123
Light source BL-7000	Class IIa	Light source BL-7000	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope ED-580T	Class IIa	Video Endoscope ED-580T	Certificate # G1 020011 0048 rev 01 NB # 0123

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ultrasonic Endoscope EG-580UR	Class IIa	Ultrasonic Endoscope EG-580UR	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EB-530XT	Class IIa	Video Endoscope EB-530XT	Certificate # G1 020011 0048 rev 01 NB # 0123
Ultrasonic Processor SU-1	Class IIa	Ultrasonic Processor SU-1	Certificate # G1 020011 0048 rev 01 NB # 0123
Endoscopy Support Program EW10-EC02	Class IIa	Endoscopy Support Program EW10-EC02	Certificate # G1 020011 0048 rev 01 NB # 0123
SYNAPSE 3D	Class IIa	SYNAPSE 3D	Certificate # G1 020011 0048 rev 01 NB # 0123
FCR CAPSULA X	Class IIa	FCR CAPSULA X	Certificate # G1 020011 0048 rev 01 NB # 0123
FCR CAPSULA XL II	Class IIa	FCR CAPSULA XL II	Certificate # G1 020011 0048 rev 01 NB # 0123
AMULET SOPHINITY	Class IIb	FUJIFILM Digital Mammography System AMULET Innovality MAMMOASCENT AWS-h	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO III G80i	Class IIa	FDR D-EVO II DR-ID 1270 / FDR ES FDR D-EVO GL FDR D-EVO III	Certificate # G1 020011 0048 rev 01 NB # 0123
FCR PRIMA Ⅱ	Class IIa	FCR PRIMA	Certificate # G1 020011 0048 rev 01 NB # 0123
FCR PRIMA T **FCR PRIMA T2** **FCR PRIMA Tm**	Class IIa	FCR PRIMA T	Certificate # G1 020011 0048 rev 01 NB # 0123
AMULET Bellus II	Class IIa	AMULET Bellus II	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR SE Console	Class IIa	FDR SE Console	Certificate # G1 020011 0048 rev 01 NB # 0123
DR-ID 800CL	Class IIa	DR-ID 800CL	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR nano **FDR AQRO**	Class IIb	FDR nano	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EN-580T (EMDN: Z120206)	Class IIa	Video Endoscope EN-580T	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EN-580T (EMDN: Z120205)	Class IIa	Video Endoscope EN-580T	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EN-580XP (EMDN: Z120206)	Class IIa	Video Endoscope EN-580XP	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EN-580XP (EMDN: Z120205)	Class IIa	Video Endoscope EN-580XP	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EG-600WR	Class IIa	Video Endoscope EG-600WR	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-600WM	Class IIa	Video Endoscope EC-600WM	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-600WI	Class IIa	Video Endoscope EC-600WI	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EC-600WL	Class IIa	Video Endoscope EC-600WL	Certificate # G1 020011 0048 rev 01 NB # 0123

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Video Endoscope EI-580BT (EMDN: Z120205)	Class IIa	Video Endoscope EI-580BT	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EI-580BT (EMDN: Z120206)	Class IIa	Video Endoscope EI-580BT	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EI-740D/S (EMDN: Z120205)	Class IIa	Video Endoscope EI-740D/S	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope EI-740D/S (EMDN: Z120206)	Class IIa	Video Endoscope EI-740D/S	Certificate # G1 020011 0048 rev 01 NB # 0123
Ultrasonic Endoscope EB-530US	Class IIa	Ultrasonic Endoscope EB-530US	Certificate # G1 020011 0048 rev 01 NB # 0123
Endoscopic CO_2 Regulator GW-100	Class IIa	Endoscopic CO_2 Regulator GW-100	Certificate # G1 020011 0048 rev 01 NB # 0123
Balloon Controller PB-30	Class IIa	Balloon Controller PB-30	Certificate # G1 020011 0048 rev 01 NB # 0123
Balloon for Ultrasonography BS-102	Class IIa	Balloon for Ultrasonography BS-102	Certificate # G1 020011 0048 rev 01 NB # 0123
Instrument Channel Tube JT-3RC	Class IIa	Instrument Channel Tube JT-3RC	Certificate # G1 020011 0048 rev 01 NB # 0123
Instrument Channel-Joint Tube JT-3RC2	Class IIa	Instrument Channel-Joint Tube JT-3RC2	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR Xair II	Class IIb	Portable X-ray unit FDR Xair	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO Mobile Compo	Class IIa	FDR D-EVO Mobile Compo	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR D-EVO Advanced	Class IIa	FDR D-EVO Advanced	Certificate # G1 020011 0048 rev 01 NB # 0123
DR-ID900CL	Class IIa	DR-ID900CL	Certificate # G1 020011 0048 rev 01 NB # 0123
FDR Smart FGX Series	Class IIb	FDR Smart FGX Series	Certificate # G1 020011 0048 rev 01 NB # 0123
MV-SR657EG	Class IIa	FUJIFILM Digital Mammography CAD MV-SR657EG	Certificate # G1 020011 0048 rev 01 NB # 0123
Pump Tube MK-1JW	Class IIa	Water pump JW-2	Certificate # G1 020011 0048 rev 01 NB # 0123
Connecting Tube CT-1JW	Class IIa	Water pump JW-2	Certificate # G1 020011 0048 rev 01 NB # 0123
Pump Cartridge PU-1JW	Class IIa	Water pump JW-2	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Supply Adapter AJ-500L	Class IIa	Water pump JW-2	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-1000JW	Class IIa	Water pump JW-2	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Supply Adapter JA-500	Class IIa	Video Endoscope EC-530WL3 -H-	Certificate # G1 020011 0048 rev 01 NB # 0123
Gas Tube CT-11G	Class IIa	Endoscopic CO2 Regulator GW-100	Certificate # G1 020011 0048 rev 01 NB # 0123
Balloon BS-2	Class IIa	Balloon BS-2	Certificate # G1 020011 0048 rev 01 NB # 0123

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Balloon for Ultrasonography B20UR	Class IIa	Balloon for Ultrasonography B20UR	Certificate # G1 020011 0048 rev 01 NB # 0123
Balloon for Ultrasonography B20UT	Class IIa	Balloon for Ultrasonography B20UT	Certificate # G1 020011 0048 rev 01 NB # 0123
Distal End Cap DC-07D	Class IIa	Video Endoscope ED-580T	Certificate # G1 020011 0048 rev 01 NB # 0123
Distal End Cap DC-06D	Class IIa	Video Endoscope ED-530XT8	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-4	Class IIa	Water Tank WT-4	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-603	Class IIa	Water Tank WT-603	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-604G	Class IIa	Water Tank WT-604G	Certificate # G1 020011 0048 rev 01 NB # 0123
Water Tank WT-04G	Class IIa	Water Tank WT-04G	Certificate # G1 020011 0048 rev 01 NB # 0123
Tube JT-500	Class IIa	Video Endoscope EC-600WM	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope ED-530XT8	Class IIa	Video Endoscope ED-530XT8	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope ER-530S2	Class IIa	Video Endoscope ER-530S2	Certificate # G1 020011 0048 rev 01 NB # 0123
Video Endoscope ER-530T	Class IIa	Video Endoscope ER-530T	Certificate # G1 020011 0048 rev 01 NB # 0123
Probe P2615-L	Class IIa	Probe P2615-L	Certificate # G1 020011 0048 rev 01 NB # 0123
Probe P2620-L	Class IIa	Probe P2620-L	Certificate # G1 020011 0048 rev 01 NB # 0123

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-01-12	FUJIF_CL607_2024-01-12	Initial issue
2024-01-22	FUJIF_CL607_2024-01-22	Corrected identification of substitute device in Table 2.
2024-02-05	FUJIF_CL607_2024-02-05	Corrected 4 of MDR Devices' classification
2024-06-03	FUJIF_CL607_2024-06-03	Changed table 2 to table 1