Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Terumo Corporation
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Contact

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Date March 06, 2024

Notified Body Confirmation Letter
Reference. : TC_CL607_2024-03-06

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:

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan
SRN Number: JP-MF-000017478

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.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD certificate expiry.

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, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa

On behalf of the Notified Body

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
Destination (sheath, dilator, valve, dailator retaining clip)	Class III	Destination	ID 60134974 0001 (NB#0197) HD 60145252 0001 (NB#0197)
TERUMO Syringe	Class IIa	N/A	HD 60145252 0001 (NB#0197)
SURFLASH	Class IIa	Surflash	HD 60145252 0001 (NB#0197)
VERSATUS	Class IIa	Versatus	HD 60145252 0001 (NB#0197)
Heartrail II	Class III	N/A	ID 60149274 0001 (NB#0197) HD 60145252 0001 (NB#0197)
Blood Bags with Anticoagulant/ Preservation Solution(Leukocyte Removal Filter integrated type)	Class III	N/A	HD 60145252 0001 (NB#0197)
TERUFLEX Transfer Bags	Class IIb	TERUMO Transfer Bags	HD 60145252 0001 (NB#0197)
IMUGARD III-RC (with blood bags)	Class IIb	IMUGARD III-RC	HD 60145252 0001 (NB#0197)
IMUGARD III-RC (without blood bags)	Class IIa	IMUGARD III-RC	HD 60145252 0001 (NB#0197)
RADIFOCUS OPTITORQUE	Class III	N/A	ID 60149172 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS ANGIOGRAPHIC CATHETER	Class III	N/A	ID 60149266 0001 (NB#0197) HD 60145252 0001 (NB#0197)
TERUFUSION BLOOD ADMINISTRATION SET	Class IIa	TERUFUSION Blood Administration Set	HD 60145252 0001 (NB#0197)
FINETOUCH Lancet	Class IIa	N/A	HD 60145252 0001 (NB#0197)
MEDISAFE Lancet for FINETOUCH	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Immucise Intradermal Injection System	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Immucise Intradermal Injection needle	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Immucise Syringe	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Teruflex Blood Bag without Anticoagulant	Class IIb	TERUMO Blood Bag without Anticoagulant	HD 60145252 0001 (NB#0197)
Outlook	Class III	OUTLOOK	ID 60148413 0001 (NB#0197) HD 60145252 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Radifocus Glidecath	Class III	RADIFOCUS GLIDECATH	ID 60148569 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS GUIDE WIRE M	Class III	N/A	ID 60156558 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS GUIDE WIRE GT with Gold Coil	Class III	N/A	ID 60156558 0001 (NB#0197) HD 60145252 0001 (NB#0197)
MEDISAFE WITH Main Pump Unit	Class IIb	MEDISAFE WITH-Main Pump Unit, REF MZ*PP01T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Cartridge	Class IIb	MEDISAFE WITH-Cartridge, REF MZ*PC10T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Remote Control	Class IIb	MEDISAFE WITH-Remote Control, REF MZ*PR01T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Filling Device	Class IIa	MEDISAFE WITH-Filling Device, REF MZ*PF01T	HD 60145252 0001 (NB#0197)
RADIFOCUS Glidewire Advantage	Class IIa	Radifocus Glidewire Advantage	HD 60145252 0001 (NB#0197)
Single Use Guidewire	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Glidesheath Slender (sheath, dilator, mini guide wire, entry needle, guide inserter)	Class IIa	Glidesheath Slender	HD 60145252 0001 (NB#0197)
RADIFOCUS INTRODUCER II (sheath, dilator, mini guide wire, entry needle, syringe, scalpel and guide inserter)	Class IIa	RADIFOCUS INTRODUCER II	HD 60145252 0001 (NB#0197)
RADIFOCUS Obturator	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Vessel Dilator	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Haemostasis Valve II	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Guide Wire M Non-vascular	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Outlook Peripheral Use	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Navicross (0.018 inch)	Class IIa	NaviCross	HD 60145252 0001 (NB#0197)
Navicross (0.035 inch)	Class IIa	NaviCross	HD 60145252 0001 (NB#0197)
TERUFUSION SS 10	Class IIb	TERUFUSION Syringe Pump Type SS3	HD 60145252 0001 (NB#0197)
TERUFUSION SS 10 TCI	Class IIb	TERUFUSION Syringe Pump Type SS3TCI / TERUFUSION Syringe Pump Type SS3OTCI	HD 60145252 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TERUFUSION LF(TBD)	Class IIb	TERUFUSION Infusion Pump Type LF3	HD 60145252 0001 (NB#0197)
TERUFUSION LM(TBD)	Class IIb	TERUFUSION Infusion Pump Type LM3	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Infusion Set	Class IIa	MEDISAFE WITH-Infusion Set, REF MZ*PS10T	HD 60145252 0001 (NB#0197)
IMUGARD III-PL (without blood bags)	Class IIa	IMUGARD III-PL	HD 60145252 0001 (NB#0197)
IMUGARD III-PL (blood bags)	Class IIb	IMUGARD III-PL	HD 60145252 0001 (NB#0197)
RADIFOCUS Glidewire Advantage Track	Class IIa	Radifocus Glidewire Advantage	HD 60145252 0001 (NB#0197)
Tercross	Class IIa	N/A	HD 60145252 0001 (NB#0197)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/01	TC_CL607_Destination_2023-12-01	Initial issue
2024/03/01	TC_CL607_2024-03-01	Products addition (44 items)
2024/03/06	TC_CL607_2024-03-06	Add Certificate Reference for IMUGARD III-PL (blood bags)