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TÜV SÜD Product Service GmbH· · Germany

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Your reference/letter of	Our reference	Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter

CL 002374 0010 Rev. 01

Reference: TPS3292_AR_Is | TSSA/MHS/2024/046 | TPS3292_AR_IIa_IIb

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: IL-MF-000010010

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR 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, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL 002374 0010

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-13

TÜV SÜD Product Service GmbH
Medical and Health Services

RAVI H A
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

F. Eckert
Franziska Eckert
2024.09.13
13:01:21 +02'00'

Franziska Eckert
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
BUDI (+ device name): 7296183URIMETRIX9K (Urimetrix)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183THORAMETRIXJN (Thorametrix)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183DRAINAGEBULBSKY (Drainage bag)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183PTCA9P (PTCA Accessories kit)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183DRAPESTOWELS8F (Drapes and towels)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183GENERALSURGERYA9 (General Surgery Pack)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183GOWNS7W (Gowns)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183LEGGINGSAV (Legging)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183GYNPACKSMD (Gynecological packs)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183HEARTPACKSAN (Heart packs)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183OPHTHALMICPACKKG (Ophthalmic packs)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183POUCHESDX (Pouches and Waste Bag)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
BUDI (+ device name): 7296183PROTECTCOVERINGSC9 (Protective covers and sharp stop)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183SURGIACCESSORMQ (Bowl packs)	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183SUCTIONPROBES6K (Suction connecting tubes and Yankauers)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183Vesselloops5G (Vessel loops)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 002374 0006 Rev.00; NB# 0123
BUDI (+ device name): 7296183CHESTDRAINAGEV5 (Thoracic catheter/ Gravitation drainage set/ Pneumothorax Catheter/ Trocar catheter)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183DRAINAGESETSN9 (Drainage systems)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183CARDIOPLEGIAN3 (Cardioplegia administration Set)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183ARTERIALLINE5G (Arterial Line - blood pressure monitoring sets)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183IRRIGATIONLX (3-way Irrigation Catheter)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183IRRIGATIONLINES4Y (Irrigation Set)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183INFUSIONLINESP8 (Infusion Sets)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
BUDI (+ device name): 7296183ANGIOGRAPHICQZ (Angiographic syringes)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183TSCLJ (Foley catheter with temperature sensor)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183NEPHROSTOMY&BILIXS (Nephrostomy & Biliary Drainage Catheters)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183ARTERIALCATHETERYZ (Arterial Catheters)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183ADMINISTRATSET6V (Administration and / or monitoring sets)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183INITIATIONPACKKR (Initiation pack kit)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183FOLEYCATHETER68 (2 way Foley catheter)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183OBSTETRICSGYNQB (Obstetrics &Gynecology pack)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123
BUDI (+ device name): 7296183POSTOPERATIVE9A (Surgical and post-operative care kits)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 002374 0005 Rev.00; NB# 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT 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 during application review)	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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-03	TPS3292_AR_Is | TSSA/MHS/2024/046	Initial issue
2024-09-13	TPS3292_AR_IIa_IIb	Addition of Basic UDI-DIs: 7296183PTCA9P, 7296183DRAPESTOWELS8F, 7296183GENERALSURGERYA9, 7296183GOWNS7W, 7296183LEGGINGSAV, 7296183GYNPACKSMD, 7296183HEARTPACKSAN, 7296183OPHTHALMICPACKKG, 7296183POUCHESDX, 7296183PROTECTCOVERINGSC9, 7296183SURGIACCESSORMQ, 7296183Vesselloops5G, 7296183CHESTDRAINAGEV5, 7296183DRAINAGESETSN9, 7296183CARDIOPLEGIAN3, 7296183ARTERIALLINE5G, 7296183IRRIGATIONLX, 7296183IRRIGATIONLINES4Y, 7296183INFUSIONLINESP8, 7296183ANGIOGRAPHICQZ, 7296183TSCLJ, 7296183NEPHROSTOMY&BILIXS, 7296183ARTERIALCATHETERYZ, 7296183ADMINISTRATSET6V, 7296183INITIATIONPACKKR, 7296183FOLEYCATHETER68, 7296183OBSTETRICSGYNQB, 7296183POSTOPERATIVE9A; Change of classification from Is to IIa for devices under Basic UDI-DI 7296183SUCTIONPROBES6K