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Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 · Germany

Fresenius Medical Care AG
Else-Kröner-Str. 1
61352 Bad Homburg

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
CBW 77174 Wolfgang Decker		Anne Schwarz		2024-05-16	1 of 30

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 077174 0017 Rev. 01**

Reference: 713329919

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: DE-MF-000008193

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
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VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Products
Ridlerstr. 65
80339
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





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=cert:CL_077174_0017_Rev._01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-16

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to be 'Anne Schwarz', written over a horizontal line.

Anne Schwarz
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to be 'Fatlume Bahtiri', written over a horizontal line.

Fatlume Bahtiri
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
F-series dialyzers: 4039361-0000-0000-0012-N2	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
FX class dialyzers: 4039361-0000-0000-0013-N5	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
FX classix dialyzers: 4039361-0000-0000-0014-N8	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
FX CorDiax dialyzers: 4039361-0000-0000-0015-NB	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
FX CorAL dialyzers: 4039361-0000-0000-0016-NE	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Acute dialyzers: 4039361-0000-0000-0017-NH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Plasma filters: 4039361-0000-0000-0018-NL	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Plasma fractionators: 4039361-0000-0000-0019-NP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fluid filters: 4039361-0000-0000-0021-N4	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 & G10 077174 0005 NB ID: 0123 Dialysers and Filters for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
DALI adsorbers: 4039361-0000-0000-0034-NJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Adsorber for therapeutic apheresis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Globaffin adsorbers: 4039361-0000-0000-0035-NM	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Adsorber for therapeutic apheresis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4008 haemodialysis tubing sets - EO: 4039361-0000-0000-0113-NC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
4008 haemodialysis tubing sets - irradiation: 4039361-0000-0000-0131-NG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
5008 haemodialysis tubing sets: 4039361-0000-0000-0114-NF	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
6008 haemodialysis tubing sets: 4039361-0000-0000-0115-NJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Genius acute dialysis tubing sets: 4039361-0000-0000-0116-NM	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
multiFiltrate acute dialysis tubing sets: 4039361-0000-0000-0117-NQ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Apheresis tubing sets: 4039361-0000-0000-0045-NS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Pressure sensor accessories: 4039361-0000-0000-0125-NP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion and priming accessories - EO: 4039361-0000-0000-0127-NV	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Infusion and priming accessories - irradiation: 4039361-0000-0000-0133-NN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Luer connection accessories - EO: 4039361-0000-0000-0128-NY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Luer connection accessories - irradiation: 4039361-0000-0000-0134-NR	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Peritoneal dialysis tubing sets - EO: 4039361-0000-0000-0042-NH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Peritoneal dialysis tubing sets - moist heat: 4039361-0000-0000-0135-NU	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Peritoneal dialysis auxiliary sets - EO: 4039361-0000-0000-0043-NL	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Peritoneal dialysis auxiliary sets - moist heat: 4039361-0000-0000-0136-NX	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PD catheters: 4039361-0000-0000-0027-NN	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PD catheter adaptors : 4039361-0000-0000-0023-NA	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
PD drainage sets : 4039361-0000-0000-0022-N7	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PD closure caps - EO: 4039361-0000-0000-0024-ND	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
PD closure caps - irradiation: 4039361-0000-0000-0130-ND	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PD closure caps - non-sterile: 4039361-0000-0000-0129-P3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
PD transfer set adaptors: 4039361-0000-0000-0025-NG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PD catheter extensions: 4039361-0000-0000-0026-NK	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Catheters and Accessories for haemodialysis and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Citrosteril: 4039361-0000-0000-0059-PB	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Cleaning and disinfectant agents or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Liquid off-line acid concentrates (cannister): 4039361-0000-0000-0049-P6	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Liquid off-line acid concentrates flexpack: 4039361-0000-0000-0050-NG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dry off-line acid concentrates (Granudial): 4039361-0000-0000-0052-NN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Dry on-line bicarbonate concentrates (Bibag): 4039361-0000-0000-0054-NU	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dry off-line bicarbonate concentrates (Granudial): 4039361-0000-0000-0055-NX	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dialysis solutions for acute treatment: 4039361-0000-0000-0032-NC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Concentrates and solutions for haemodialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
AquaA: 4039361-0000-0000-0102-N4	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
AquaBplus: 4039361-0000-0000-0103-N7	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
AquaC UNO H: 4039361-0000-0000-0104-NA	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: AquaUNO Art. No. 6328251, 6297531 AquaWTU 125 Art. No. 6325691 AquaWTU 250 Art. No.6325701	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
AquaUNO 4039361-0000-0000-0105-ND	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
AquaWTU 4039361-0000-0000-0106-NG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
CDS : 4039361-0000-0000-0109-NR	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Granumix 107S/507S: 4039361-0000-0000-0108-NN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Granumix plus: 4039361-0000-0000-0107-NK	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dialysis Water Distribution Loop: 4039361-0000-0000-0110-N3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Dialysis Concentrate Distribution Loop: 4039361-0000-0000-0111-N6	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Dialysis fluid supply equipment or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sleep safe: 4039361-0000-0000-0004-N3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
SILENCIA PD machines: 4039361-0000-0000-0005-N6	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
PD Thermosafe: 4039361-0000-0000-0123-NH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4008: 4039361-0000-0000-0003-MY	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
5008: 4039361-0000-0000-0002-MV	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
6008: 4039361-0000-0000-0001-MS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Multi: 4039361-0000-0000-0006-N9	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 G10 077174 0005 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bioimpedance devices: 4039361-0000-0000-0008-NF	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2490 & GCQ 077174 0014 NB ID: 0123 Active medical devices for extracorporeal blood treatment and peritoneal dialysis or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Connection disconnection sets: 4039361-0000-0000-0084-PB	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Apheresis rinsing solutions: 4039361-0000-0000-0031-N9	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Rinsing Solutions or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Drainage accessories -EO: 4039361-0000-0000-0126-NS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Drainage accessories - irradiation: 4039361-0000-0000-0132-NK	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
Peritoneal dialysis drainage sets - EO: 4039361-0000-0000-0044-NP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Peritoneal dialysis drainage sets - moist heat: 4039361-0000-0000-0137-P2	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input checked="" type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
PD sterile handling devices: 4039361-0000-0000-0030-N6	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G2S 024492 2491 & GCQ 077174 0016 G11 077174 0007 NB ID: 0123 Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



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
<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	713329919	Initial issue
2024-05-16	713329919	Typo Correction in G10, G11 Certificate