



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 039709 1304 Rev. 00

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies):

- Autotransfusion Systems and Associated Disposables
- Centrifugal Blood Pumps
- Bio-Console Drive Units
- Flow Monitoring Systems
- Bio-Cal Blood Temperature Controller
- Temperature Monitoring Systems and Associated Disposables
- Blood Monitoring Systems
- Cardioplegia Delivery Systems
- Disposable Blood Handling Devices used for Open Heart Surgery
- Arterial Filters
- Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs
- Cardiotomy Venous Reservoirs
- Venous Reservoir Bags
- Perfusion Equipment and Disposable Perfusion Devices
- Disposable Medical Devices for Drainage Systems
- Disposable Medical Devices for use in Extracorporeal Support: Cardioplegia, Cannulae, Catheters, Venting, Suction
- Pressure Display System & related accessories of class IIa
- Tissue Positioning/Stabilizing Devices
- Surgical Site Clearing Devices
- Intravascular Shunts
- Surgical Retractors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72157211

Valid from: 2020-04-29

Valid until: 2024-05-26

Date, 2020-04-29





**Add value.
Inspire trust.**

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

Medtronic, Inc.
710 Medtronic Parkway
55432 MINNEAPOLIS,
USA

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
39709	713238770 713230334 713255088 713255090 713260319 713261287 713261286 713260110 713267091 713309022 713336338 713307821 713315288 713335001 713223781 713223783 713250323 713239902	medical_devices@tuvsud.com	-	2024-07-22	1 of 10

**TÜV SÜD Product Service GmbH
Confirmation Letter**

CL 039709 1530 Rev. 01

**Reference: 713238770 | 713230334 | 713255088 | 713255090 | 713260319 | 713261287 |
713261286 | 713260110 | 713267091 | 713309022 | 713336338 | 713307821 |
713315288 | 713335001 | 713223781 | 713223783 | 713250323 | 713239902**

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: US-MF-000019977

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
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 Devices
Ridlerstr. 65
80339 Munich
Germany

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





- 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:

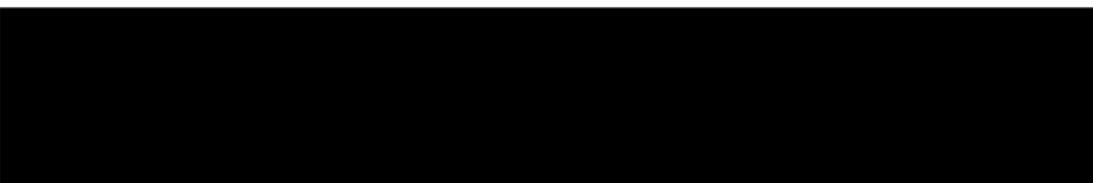
- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class 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_039709_1530

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-22



Kathryn Dafoe
Conformity Assessment Responsible (CARE)

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
<p>Basic UDI-DI 0763000B000114178</p> <p>Octopus Evolution / Evolution AS</p> <p>Models TS2500 TS2000</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00; NB# 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B00009648M</p> <p>Octopus Nuvo Tissue Stabilizer</p> <p>Model TSMICS1</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00; NB# 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B00013237G</p> <p>Cardioblate CryoFlex Surgical Ablation Probes</p> <p>Models 60SF2 60SF3 60SF7</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1295 Rev. 00; NB# 0123 Certificate # G7 039709 1309 Rev. 00; NB # 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B00013247J</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1295 Rev. 00; NB# 0123</p>



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
Cardioblate CryoFlex Clamp and Surgical Ablation Probe Model 60CM1	<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 type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	Certificate # G7 039709 1309 Rev. 00; NB # 0123 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#
Basic UDI-DI 0763000B000120273 CG Future™ 638B Annuloplasty Band Models 638BL26 638BL28 638BL30 638BL32 638BL34 638BL36 638BL38	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 1025 Rev. 01; NB # 0123 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#
Basic UDI-DI 0763000B000120579 Freestyle Aortic Obturators Model 7990SET	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 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#
Basic UDI-DI 0763000B00012067B Freestyle Bioprosthesis Models FR995-19 FR995-21 FR995-23 FR995-25	<input checked="" 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"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 0945 Rev. 02; NB # 0123 or



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
FR995-27 FR995-29	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		<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#
Basic UDI-DI 0763000B00012087F Mosaic Bioprosthesis / Ultra Bioprosthesis Models 305C219 305C221 305C223 305C225 305C227 305C229 310C25 310C27 310C29 310C31 310C33 305U219 305U221 305U223 305U225 305U227 305U229	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 0945 Rev. 02; NB # 0123 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#
Basic UDI-DI 0763000B00012147A Hancock II bioprosthesis / Ultra bioprosthesis Models T505C221 T505C223 T505C225 T505C227 T505C229 T510C25 T510C27 T510C29 T510C31 T510C33 T505U221 T505U223 T505U225 T505U227 T505U229	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 0945 Rev. 02; NB # 0123 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
<p>Basic UDI-DI 0763000B000128887</p> <p>Streamline 6491 Unipolar Pediatric Temporary Pacing Lead</p> <p>Streamline 6492 Unipolar Temporary Atrial Pacing Lead</p> <p>Models 6491F 6492F</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate # G1 039709 1279 Rev. 00; NB# 0123</p> <p>Certificate # G7 039709 1272 Rev. 00; NB # 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B00014367W</p> <p>Mosaic Mitral Obturators</p> <p>Model 7310</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate # G1 039709 1279 Rev. 00; NB# 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B00014377Y</p> <p>Hancock II™ aortic obturators</p> <p>Hancock II™ mitral obturators</p> <p>Models 7505SET 7510SET</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate # G1 039709 1279 Rev. 00; NB# 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>Basic UDI-DI 0763000B000143984</p> <p>Open Pivot Sizer Set STD/AP360</p> <p>Open Pivot Std/AVG Sizer Set</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate # G1 039709 1279 Rev. 00; NB# 0123</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had</p>



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
Open Pivot AP360 Sizer Set Models 576 577 578	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Basic UDI-DI 0763000B00014407M Medtronic Open Pivot Heart Valve Models 500DM21 500DM23 500DM25 500DM27 500DM29 500DM31 505DA16 505DA22 505DA24 505DA28 500DM33 500FA19 500FA21 500FA31 500FA27 500FA25 500FA23 505DM18 505DM20 505DM22 505DM26 505DM28 505DM24 500FA29 505DA18 505DA20 505DA26 505DM16 500DM19	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1295 Rev. 00; NB# 0123 Certificate # G7 039709 1073 Rev. 01; NB # 0123 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#
Basic UDI-DI 0763000B00014417P Medtronic Open Pivot Aortic Valved Graft Models 502AG21 502AG23 502AG27 502AG31 502AG25	<input checked="" 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 type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1295 Rev. 00; NB# 0123 Certificate # G7AO 039709 0988 Rev. 02; NB # 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had



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
502AG29 502AG33	<input type="checkbox"/> Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Basic UDI-DI 0763000B000146789 Medtronic Aortic Punch Models APU560 APU556 APU552 APU550 APU544 APU540 APU535 APU525 APU460 APU456 APU452 APU450 APU448 APU444 APU440 APU435 APU430 APU425 APU530 APU548	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 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#
Basic UDI-DI 0763000B00015057Q Contour 3D™ Annuloplasty Ring Models 690R26 690R28 690R30 690R32 690R34 690R36	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 0990 Rev. 01; NB # 0123 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#
Basic UDI-DI 0763000B00015067S Contour 3D™ Sizers Model	<input checked="" 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"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 or



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
7690S	<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"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<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#
Basic UDI-DI 0763000B00015748B Profile 3D 680R Annuloplasty Band Models 680R40 680R38 680R36 680R34 680R32 680R30 680R28 680R26 680R24	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 Certificate # G7 039709 1020 Rev. 01; NB # 0123 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#
Basic UDI-DI 0763000B00015758D Profile 3D™ 7680 Sizer Set Model 7680S	<input checked="" 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 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:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1279 Rev. 00; NB# 0123 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
Not applicable	<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
2024-05-31	713238770 713230334 713255088 713255090 713260319 713261287 713261286 713260110 713267091 713309022 713336338 713307821 713315288 713335001 713223781 713223783 713250323 713239902	Initial issue
2024-07-22	713238770 713230334 713255088 713255090 713260319 713261287 713261286 713260110 713267091 713309022 713336338 713307821 713315288 713335001 713223781 713223783 713250323 713239902	Correction of Typo on G7AO 039709 0988 Rev.02 (Basic UDI-DI: 0763000B00014417P) and minor editorial changes



**Add value.
Inspire trust.**

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

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
039709	200210004653-G12CL	medical_devices@tuvsud.com	---	2024-07-24	1 of 9

TÜV SÜD Product Service GmbH Confirmation Letter

CL 039709 1543 Rev. 00

Reference: 713263538 | 713261673 | 713263543 | 713279228 | 200210004653 | 713227678 | 200210005086

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: US-MF-000019977

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
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

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

TÜV SÜD Product Service GmbH
Application Review
Ridlerstr. 65
80339 Munich
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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further 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_039709_1543_Rev._00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-24

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Kathryn Dafoe
Conformity Assessment Responsible (CARE)

Konrad Fackler
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
<p>Basic UDI-DI: 0763000B000041279</p> <p>Starfish Evo Heart Positioner</p> <p>Urchin Evo Heart Positioner</p> <p>Models: HP3000 HP3500</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B000128989</p> <p>Bio-Medicus™ Adult Venous Cannula and Introducer</p> <p>Models: 96670-125 96670-123 96670-121 96670-119 96670-117 96670-115 96670-127</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00012907S</p> <p>Bio-Medicus™ Pediatric Arterial Cannula and Introducers</p> <p>Models: 96820-108 96820-110 96820-112 96820-114</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
<p>Basic UDI-DI: 0763000B00012917U</p> <p>Bio-Medicus™ Adult Cannula and Introducer</p> <p>Models: 96570-115 96570-117 96570-119 96570-121 96570-123 96570-125</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00012927W</p> <p>Bio-Medicus™ Adult Cannula Kit</p> <p>Models: 96530-115 96530-117 96530-119 96530-121 96530-123 96530-125</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00012937Y</p> <p>Bio-Medicus™ Pediatric Venous Cannula and Introducers</p> <p>Models: 96830-108 96830-110 96830-112 96830-114</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
<p>Basic UDI-DI: 0763000B000129482</p> <p>Bio-Medicus™ Adult Venous Cannula Kit</p> <p>Models: 96600-115 96600-117 96600-119 96600-121 96600-123 96600-125 96600-127 96600-129</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B000129584</p> <p>Bio-Medicus™ Insertion Kit</p> <p>Models: 96551 96552 96553</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00014467Z</p> <p>DLP™ Aortic Root Cannulae</p> <p>Models: 10018 10016 10014 10012 10009</p>	<p><input checked="" 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 type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
<p>Basic UDI-DI: 0763000B000144783</p> <p>DLP™ Aortic Root Cannulae</p> <p>Models: 12218</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B000144885</p> <p>DLP™ Aortic Root Cannulae</p> <p>Models: 10114 10112</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B000144987</p> <p>MiAR™ Cannulae</p> <p>Models: 11012L 11014L</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
<p>Basic UDI-DI: 0763000B00014507Q</p> <p>DLP™ Aortic Root Cannulae</p> <p>Models: 11012 11014</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00014527U</p> <p>DLP™ Dual Lumen Aortic Root Cannulae with Vent Line</p> <p>Models: 30401</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00014537W</p> <p>DLP™ Cardioplegia Needles</p> <p>Models: 10313 11316</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
<p>Basic UDI-DI: 0763000B00021137A</p> <p>DLP™ Femoral Arterial Cannulae</p> <p>Models: 57414 57417</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>
<p>Basic UDI-DI: 0763000B00022907Z</p> <p>Bio-Medicus Life Support Cannula and Introducer</p> <p>Models: LS96010-009 LS96010-011 LS96010-013 LS96010-015 LS96110-009 LS96110-011 LS96110-013 LS96110-015 LS96218-015 LS96218-017 LS96218-019 LS96218-021 LS96218-023 LS96218-025 LS96550-015 LS96550-017 LS96555-019 LS96555-021 LS96555-023 LS96555-025 LS96438-021 LS96438-023 LS96438-025 LS96355-021</p>	<p><input checked="" type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD</p> <p>Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate # G1 039709 1304 Rev. 00 G7 039709 1326 Rev. 00 NB# 0123</p> <p>or</p> <p><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#</p>



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
LS96360-023 LS96360-025 LS96360-027 LS96360-029			

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	<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
2024-07-24	200210004653-G12CL	Initial issue