To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2024-05-22

Our reference: QS-1202

Notified Body Confirmation Letter
Certification No: 1202GB454240522

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany
SRN[2]: DE-MF-000006084

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.

[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a 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)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Urethral, prostatic and bladder catheters - accessories	Class I devices placed on the market in sterile condition	N/A	Certificate 1202DE415200310 NB 0482 1202GB415200310 NB 0482
Urethral prostatic and bladder catheters, Nelaton	Class I devices placed on the market in sterile condition	N/A	Cerfificate 1202DE415200310 NB 0482 1202GB415200310 NB 0482
Devices for percutaneous urinary drainage - Accessories	Class I devices placed on the market in sterile condition	N/A	Cerfificate 1202DE415200310 NB 0482 1202GB415200310 NB 0482
Urine collection bags	Class I devices placed on the market in sterile condition	N/A	Cerfificate 1202DE415200310 NB 0482 1202GB415200310 NB 0482
Urology measurement devices not included in other classes	Class I devices placed on the market in sterile condition Class I devices with a measuring function	N/A	Certificate 1202DE415200310 NB 0482 1202GB415200310 NB 0482 1202DE416200310 NB 0482 1202GB416200310 NB 0482
Needle introducers	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Shearing biopsy guns	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Shearing biopsy needles	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Aspiration fine needles and kits	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urological guidewires, not hydrophilic	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urological guidewires, hydrophilic	Class IIa	N/A	Certificate 1202DE410200310

			NB 0482 1202GB410200310 NB 0482
Cystomanometry catheters, without balloon	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urodynamics devices - other	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Devices for Percutaneous Urinary Drainage-accessories	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Needles for other procedures	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Sequential dilators for percutaneous nephrostomy	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urinary stone retrieval baskets	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, couvelaire, with balloon	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, delinotte, with balloon	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, dufour, with balloon	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, with balloon – other	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Ureteral catheters with cylindrical tip	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Ureteral catheters with chevassu tip	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482

Ureteral catheters without balloon	Class IIa	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, not self-retained - other	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, with balloon - other	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, nelaton, with balloon	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Urethral prostatic and bladder catheters, tiemann with balloon	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Single loop ureteral stents	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Double loop ureteral stents	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Devices for suprapubic urinary drainage - other	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Devices for percutaneous nephrostomy - other	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482
Nephrostomy catheters	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1202DE410200310 NB 0482 1202GB410200310 NB 0482

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-05-22	1202GB454240522	Initial issue