servoprax GmbH
Am Marienbusch 9
46485 Wesel
Germany

Notified Body Confirmation Letter

Registration no.: D1189400022

To whom it may concern,

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

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

servoprax GmbH
Am Marienbusch 9
46485 Wesel
Germany
SRN: DE-MF-000007413

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, 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 a 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 Regulation (EU) 2023/607), 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 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, 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)

Stuttgart, 2024-09-26

Head of Notified Body

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
WING FLO Infusions-Set **Basic-UDI-DI:** **4052919A214000SE**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
ALKOTIP alcohol swab **Basic-UDI-DI:** **4052919A202000RM** **4052919A205000SA**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
ALKOTIP alcohol swab stick **Basic-UDI-DI:** **4052919A207000SQ**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
NEOPOINT disposable needle **Basic-UDI-DI:** **4052919A212000RY**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware stitch cutter **Basic UDI-DI:** **4052919A218000TA**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware scalpel blades **Basic UDI-DI:** **4052919A272000U2**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware disposable scalpel **Basic UDI-DI:** **4052919A237000TR**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
VARIO SAFE PLUS safety lancet **Basic UDI-DI:** **4052919A258000UN**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
MONOCLIX / mediware blood lancet **Basic UDI-DI:** **4052919A230000S8**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483

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
soft-hand proFIT OP-Handschuhe **Basic UDI-DI:** **4052919A183000U7** **4052919A211000RR**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware BIOPSY PUNCH **Basic UDI-DI:** **4052919A220000RV**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT-suction connection tube **Basic UDI-DI:** **4052919A236000TJ**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DIGItemp digital Fever Thermometer **Basic UDI-DI:** **4052919A231000SF**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware hygienic protection cover **Basic UDI-DI:** **4052919A206000SH**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware proctoscope **Basic UDI-DI:** **4052919A222000SB**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware disposable syringe **Basic UDI-DI:** **4052919A219000TH**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware disposable tweezer **Basic UDI-DI:** **4052919A192000UB**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483

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
mediware vaginal specula **Basic UDI-DI: 4052919A181000TR**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware SERVODROP IG Infusion Set Basic UDI-DI: 4052919A201000RE	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware irrigation syringe **Basic UDI-DI: 4052919A178000UX**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware sterile drapes **Basic-UDI-DI: 4052919A187000V3**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware instrument tray cover **Basic UDI-DI: 4052919A274000UG**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483

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
mediware disposable surgical gown **Basic UDI-DI: 4052919A184000UE**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
URI-MAX adhesive urine collector **Basic UDI-DI: 4052919A195000UY**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
DCT-urine bag **Basic UDI-DI: 4052919A193000UR**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
soft-hand COPOLYMER examination glove **Basic UDI-DI: 4052919A182000TY**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
soft-hand clean examination glove **Basic UDI-DI: 4052919A183000U7**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483

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
mediware irrigation syringe **Basic UDI-DI: 4052919A189000VH**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware skin marker **Basic UDI-DI: 4052919A198000VM**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
celltip GYN ECONOMY smear brush **Basic UDI-DI: 4052919A186000UU**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
NEOPOINT blunt fill needle **Basic UDI-DI: 4052919A268000UZ**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
PRESSURE MAN II **Basic UDI-DI: 4052919A176000UH**	Class I devices with a measuring function	N/A	Certificate Registration no. D1189400007, NB # 0483

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
silcoat Latex Foley Catheter **Basic UDI-DI: 4052919A243000T8**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate Registration no. D1189400006, NB # 0483
silclear Silicone Foley Catheter **Basic UDI-DI: 4052919A241000SS**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
ENDO-BREEZER Endotracheal Tube Kit **Basic-UDI-DI: 4052919A270000TL**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
ENDO-STYLET Alluminium Intubation Mandrin **Basic-UDI-DI: 4052919A271000TT**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
ENDO-BREEZER Endotracheal Tube **Basic-UDI-DI: 4052919A213000S7**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware Extension Tube **Basic-UDI-DI: 4052919A233000SY**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT - Nelaton Catheter **Basic-UDI-DI: 4052919A209000T6**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT – Suction Catheter **Basic-UDI-DI: 4052919A208000SX**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT – Oxygen Mask **Basic UDI-DI: 4052919A229000TU**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT – Nasal Oxygen Cannulas **Basic UDI-DI: 4052919A234000T4**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483

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
DCT – Oxygen Catheter **Basic UDI-DI: 4052919A210000RJ**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
DCT – Nebulizer **Basic UDI-DI: 4052919A238000TY**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware JELLY DEST Syringe filled with Lubricant Jell **Basic UDI-DI: 4052919A254000TS**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
RESQ-BREEZER SILICONE LINE II Resuscitator **Basic UDI-DI: 4052919A257000UF**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
RESQ-BREEZER CLEARLINE II Resuscitator **Basic UDI-DI: 4052919A256000U8**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
RESQ-BREEZER SILICONE Ventilation Mask **Basic UDI-DI: 4052919A255000TZ**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
RESQ-BREEZER PVC Ventilation Mask **Basic UDI-DI: 4052919A273000U9**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
RESQ-BREEZER Silicone Ventilation Mask **Basic UDI-DI: 4052919A216000SU**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
LIFEGUARD POCKET-BREEZER Foldable Mask **Basic UDI-DI: 4052919A215000SM**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
OPTIDROP ULTRA MEDICAL **Basic UDI-DI: 4052919A242000SZ**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483

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
OZONE VACUUM BOTTLE **Basic UDI-DI: 4052919A227000TE**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware Intravenous Cannula **Basic UDI-DI: 4052919A221000S4**	Class IIa	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware INFUSIONS SET **Basic UDI-DI: 4052919A200000R7**	Class I devices placed on the market in sterile condition	N/A	D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
DCT – Rectal Tube **Basic UDI-DI: 4052919A178000UX**	Class I devices placed on the market in sterile condition	N/A	D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
mediware Disposable Syringe **Basic UDI-DI: 4052919A219000TH**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400014, NB # 0483 Certificate Registration no. D1189400018, NB # 0483
mediware AQUA - GLYCO / AQUA DEST **Basic UDI-DI: 4052919A19300UJ**	Class I devices placed on the market in sterile condition	N/A	D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
AIRWAY-BREEZER Oropharyngeal airway **Basic UDI-DI: 4052919A179000V6**	Class I devices placed on the market in sterile condition	N/A	D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483

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
servoderm Wound Dressing **Basic UDI-DI: 4052919A180000TJ**	Class I devices placed on the market in sterile condition	N/A	D1189400013, NB # 0483 Certificate Registration no. D1189400020, NB # 0483 Certificate Registration no. D1189400019, NB # 0483 Certificate Registration no. D1189400016, NB # 0483
PRESSURE MAN II DeLuxe Chrome-Line **Basic UDI-DI: 4052919A175000UA**	Class I devices placed on the market in sterile condition	N/A	Certificate Registration no. D1189400007, NB # 0483

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-09-26	D1189400022	Initial