ELCON Medical Instruments GmbH
Dr. Karl-Storz-Straße 26
78532 Tuttlingen
Germany

Notified Body Confirmation Letter

Registration no.: D1068800005

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:

ELCON Medical Instruments GmbH
Dr. Karl-Storz-Straße 26
78532 Tuttlingen
Germany
SRN: DE-MF-000005908

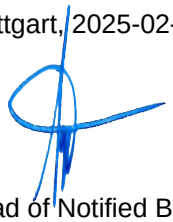
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, 2025-02-12



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
Suction Irrigation Instruments, ***Saug-/Spülinstrumente*, 404911318802A002000001SU**	IIa	N/A	Certificate Registration no. 514464 MR5; NB no. 0297

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
Forceps, *Zange*, 404911313301R002001001UD	Ir	N/A	N/A
Knife handle, *Messergriff*, 404911312701R002001001Y6	Ir	N/A	N/A
Knife/Scissors/ Punch/Wire cutting forceps, *Messer/Schere/Stanze/ Drahtschneidezange,* 404911315301R002001001X3	Ir	N/A	N/A
Amputation knife, *Amputationsmesser,* 404911316401R002001001ZP	Ir	N/A	N/A
Knife/Scissors/Punch Ophthalmology, *Messer/Schere/Stanze Ophthalmologie,* 404911315201R001001001V9	Ir	N/A	N/A
Clamp, *Klemme*, 404911313801R0020010012V	Ir	N/A	N/A
Forceps Ophthalmology, *Pinzette Ophthalmologie*, 404911313001R001001001PZ	Ir	N/A	N/A
Forceps, *Pinzette*, 404911313101R002001001RT	Ir	N/A	N/A

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
Dilatator, *Dilatator*, 404911317401R00200100135	Ir	N/A	N/A
Vascular clamp, *Gefäßklemme*, 404911313901R00200100146	Ir	N/A	N/A
Clip forceps, *Clipzange*, 404911314301R002001001VQ	Ir	N/A	N/A
Retractor, *Wundhaken*, 404911314101R002001001T6	Ir	N/A	N/A
Hook/Dissector/Depressor, *Haken/Dissektor/Depressor*, 404911311001R002001001MU	Ir	N/A	N/A
Spatula, *Spatel*, 404911314601R002001001ZK	Ir	N/A	N/A
Curette/Rasp/Scraper/ Tonsillectomy instrument, *Kürette/Raspel/Schaber/ Tonsillektomie-Instrument,* 404911310401R002001001RM	Ir	N/A	N/A
Probe, *Sonde*, 404911316301R002001001YE	Ir	N/A	N/A
Cotton applicator, *Watteträger*, 404911312401R002001001UB	Ir	N/A	N/A
Trocar, *Trokar*, 404911314901R0020010015H	Ir	N/A	N/A
Perforator, *Perforator*, 404911311501R002001001U9	Ir	N/A	N/A
Cannula, *Kanüle*, 404911315801R0020010015K	Ir	N/A	N/A
Syringe, *Spritze*, 404911317701R0020010016Y	Ir	N/A	N/A
Needle holder/Knot pusher, *Nadelhalter/Fadenführer*, 404911312901R0020010012T	Ir	N/A	N/A

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
Wire twister, *Drahtanlegezange*, 404911311201R002001001QE	Ir	N/A	N/A
Hemorrhoidal forceps, *Hämorrhoidalzange,* 404911318001R002001001X9	Ir	N/A	N/A
Biopsy forceps, *Biopsiezange*, 404911315001R002001001T8	Ir	N/A	N/A
Speculum, *Spekulum*, 404911314801R00200100148	Ir	N/A	N/A
Catheter, *Katheter*, 404911311301R002001001RP	Ir	N/A	N/A
Circumcision clamp, *Klemme Beschneidung*, 404911318301R00200100137	Ir	N/A	N/A
Forceps bone, *Zange Knochen*, 404911312801R002001001ZF	Ir	N/A	N/A
Chisel, *Meißel*, 404911311901R002001001ZD	Ir	N/A	N/A
Gouge/Trephine, *Hohlmeißelzange/Trephine*, 404911311701R002001001WT	Ir	N/A	N/A
Dissector/Elevator/ Raspatory, *Dissektor/Elevatorium/ Raspatorium,* 404911311101R002001001P5	Ir	N/A	N/A
Stripper, *Stripper*, 404911316801R0020010016W	Ir	N/A	N/A
Testing device, *Testgerät*, 404911317101R002001001X7	Ir	N/A	N/A
Obstetrical forceps, *Geburtshilfezange*, 404911316601R0020010014C	Ir	N/A	N/A
Burr, *Bohrer*, 404911314001R002001001RV	Ir	N/A	N/A

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
Guide, *Führung*, 404911318501R0020010015R	Ir	N/A	N/A
Screw driver, *Schraubendreher*, 404911312501R002001001VL	Ir	N/A	N/A
Spreader, *Spreizer*, 404911315501R002001001ZM	Ir	N/A	N/A
Saw, *Säge*, 404911312101R002001001QG	Ir	N/A	N/A
Bone clamp, *Knochenklammer,* 404911312301R002001001T2	Ir	N/A	N/A
Reamer, *Ahle*, 404911315901R0020010016U	Ir	N/A	N/A
Snare Instrument, *Schlingeninstrument*, 404911310701R002001001VG	Ir	N/A	N/A
Crushing forceps, *Quetschzange*, 404911313501R002001001WX	Ir	N/A	N/A
Spoon/Scraper Ophthalmology, *Löffel/Schaber Ophthalmologie*, 404911310301R001001001PT	Ir	N/A	N/A
Needle Ophthalmology, *Nadel Ophthalmologie*, 404911311401R001001001SF	Ir	N/A	N/A
Hooklet Ophthalmology, *Häkchen Ophthalmologie*, 404911310901R001001001XH	Ir	N/A	N/A
Chisel Ophthalmology, *Meißel Ophthalmologie*, 404911311801R001001001XK	Ir	N/A	N/A
Spatula Ophthalmology, *Spatel Ophthalmologie*, 404911314501R001001001XR	Ir	N/A	N/A
Snare instrument Ophthalmology, *Schlingeninstrument Ophthalmologie*, 404911310601R001001001TN	Ir	N/A	N/A

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
Clamp Ophthalmology, *Klemme Ophthalmologie*, 404911313701R001001001YY	Ir	N/A	N/A
Enucleation scissors Ophthalmology, *Enukleationsschere Ophthalmologie*, 404911316901R0010010017N	Ir	N/A	N/A
Trephine Ophthalmology, *Trephine Ophthalmologie*, 404911311601R001001001UZ	Ir	N/A	N/A
Dilatator Ophthalmology, *Dilatator Ophthalmologie*, 404911317301R001001001Z8	Ir	N/A	N/A
Probe Ophthalmology, *Sonde Ophthalmologie*, 404911316201R001001001WL	Ir	N/A	N/A
Cannula Ophthalmology, *Kanüle Ophthalmologie*, 404911315701R0010010013R	Ir	N/A	N/A
Self-retaining retractors, *Selbsthaltende Retraktoren*, 404911318702A002000001RK	IIa	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-02-12	D1068800005	Rev 02: correction, the product self-retaining retractors with the Basic-UDI-DI 404911318702A002000001RK is now inserted in table 2 because the products were not monitored under MDD by a notified body. Adding English product names for class IIa products
2024-08-20	D1068800003	Rev 01: Adding English product names for class Ir products Correction of a transmission error The Basic UDI-DI 404911311301R002001001RP is a catheter instead of an abdominal speculum
2024-06-17	D1068800001	Initial