BAK Kohler Medical KG
Siemensring 15
78579 Neuhausen ob Eck
Germany

Notified Body Confirmation Letter

Registration no.: D1289900014

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:

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Siemensring 15
78579 Neuhausen ob Eck
Germany
SRN: DE-MF-000005526

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, 2024-10-17

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
HF-ELECTRODES 4065597HF0001FU 4065597HF0002FW	Class IIb	N/A	D1289900008 NB#0483
HF-INSTRUMENTS & ACCESSOIRES 4065597HF0003FY 4065597HF0004G2 4065597HF0005G4 4065597HF0006G6 4065597HF0007G8 Ersatzteile / Zubehör 4065597HF0008GA 4065597HF0009GC 4065597HF0010FV 4065597HF0011FX 4065597HF0012FZ 4065597HF0013G3 4065597HF0014G5	Class IIb	N/A	D1289900008 NB#0483
SAW BLADES, Bone surgery – Orthopaedics 4065597SB0001JX 4065597SB0002JZ	Class IIa	N/A	D1289900008 NB#0483
ENDOSCOPES 4065597END001MJ 4065597END002ML 4065597END003MN 4065597END004MQ 4065597END005MS 4065597END006MU 4065597END007MW 4065597END008MY 4065597END009N2 4065597END010MK 4065597END011MM	Class IIa	N/A	D1289900008 NB#0483
TROCAR, SHEATHS & CANNULAS for various fields: laparoscopy, arthroscopy, plastic surgery, sinuscopy, urology, gynecology 4065597TRO001XE 4065597TRO009XW 4065597TRO011XH 4065597TRO014XP 4065597TRO015XR 4065597TRO016XT	Class IIa	N/A	D1289900008 NB#0483
SUCTION CANNULAS 4065597SK0004N8	Class IIa	N/A	D1289900008 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
CONNECTIONS-ADAPTER 4065597SK0005NA	Class IIa	N/A	D1289900008 NB#0483
OVARIAN NEEDLES, INSUFFLATION NEEDLES 4065597TRO012XK	Class IIa	N/A	D1289900008 NB#0483
SUCTION AND IRRIGATION CANNULAS 4065597SK0003N6	Class IIa	N/A	D1289900008 NB#0483
PORTIO ADAPTER 4065597TRO008XU	Class IIa	N/A	D1289900008 NB#0483
SUCTION AND IRRIGATION PUNCHES 4065597ST0003R9	Class IIa	N/A	D1289900008 NB#0483
TROCARS & OBTURATORS 4065597TRO010XF	Class IIa	N/A	D1289900008 NB#0483
SUCTION AND IRRIGATION TUBES 4065597SK0002N4	Class IIa	N/A	D1289900008 NB#0483
SUCTION AND IRRIGATION HANDLES & SUCTION AND IRRIGATION TUBES 4065597SK0001N2 4065597SK0002N4	Class IIa	N/A	D1289900008 NB#0483
HASSON-CONES 4065597TRO007XS	Class IIa	N/A	D1289900008 NB#0483
TROCARSTOPS 4065597TRO002XG	Class IIa	N/A	D1289900008 NB#0483
REDUCER 4065597TRO003XJ	Class IIa	N/A	D1289900008 NB#0483
REDUCER SHEATHS 4065597TRO004XL	Class IIa	N/A	D1289900008 NB#0483
SAFETY TROCARS 4065597TRO006XQ	Class IIa	N/A	D1289900008 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
PROTECTIVE TROCARS 4065597TRO005XN	Class IIa	N/A	D1289900008 NB#0483
DILATATION-SET 4065597TRO013XM	Class IIa	N/A	D1289900008 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
CLIP APPLYING FORCEPS, ENDOSCOPIC 4065597CL0001FV	Class Ir	N/A	D1289900008 NB#0483
CLIP APPLYING FORCEPS, OPEN SURGERY 4065597CL0002FX	Class Ir	N/A	D1289900008 NB#0483
KERRISON PUNCHES 4065597ST0001R5	Class Ir	N/A	D1289900008 NB#0483
RONGEURS 4065597ST0002R7	Class Ir	N/A	D1289900008 NB#0483
ARTHROSCOPY PUNCHES 4065597ST0004RB	Class Ir	N/A	D1289900008 NB#0483
ENT PUNCHES 4065597ST0005RD	Class Ir	N/A	D1289900008 NB#0483

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-10-17	D1289900014	Initial