medical bees GmbH
Friedrich-Wöhler-Straße 13
78576 Emmingen
Germany

Notified Body Confirmation Letter

Registration no.: D1357900015

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:

medical bees GmbH
Friedrich-Wöhler-Straße 13
78576 Emmingen
Germany
SRN: MF-000005814

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, 2025-01-17

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
Powertool, handpiece 042515541TD02PTHANDPIECHT	IIa	n.a.	D1357900011 NB#0483
Powertool, powerpack 042515541TD02PTPOWERPAC39	IIa	n.a.	D1357900011 NB#0483
Powertool, charging device 042515541TD02PTCHARGEFT	IIa	n.a.	D1357900011 NB#0483
Powertool, attachment 042515541TD02PTATTACHML7	IIa	n.a.	D1357900011 NB#0483
Ring Retraktor und Komponenten 042515541TD05RINGRETRAKRR	IIa	n.a.	D1357900011 NB#0483
Schädelklemmensystem und Komponenten, Variante Kunststoff 042515541TD05SCHAEDKUN8Z	IIa	n.a.	D1357900011 NB#0483
Schädelklemmensystem und Komponenten 042515541TD05SCHAEDY5	IIa	n.a.	D1357900011 NB#0483
Retraktor und Komponenten 042515541TD05RETRAK5U	IIa	n.a.	D1357900011 NB#0483
Retraktor und Komponenten, Variante Kunststoff 042515541TD05RETRAKKUNNW	IIa	n.a.	D1357900011 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
Adenotom 042515541TD0301ADENOTOMWC	Ir	n.a.	n.a.
Kürette 042515541TD0301KUERETTECK	Ir	n.a.	n.a.
Knochenfeile 042515541TD0301KNOFEILE6B	Ir	n.a.	n.a.
Raspel 042515541TD0301RASPELKJ	Ir	n.a.	n.a.
Reibahle, orthopädisch 042515541TD0301REIBAHLEYR	Ir	n.a.	n.a.
Tonsillektomie-Instrument 042515541TD0301TONSILLMQ	Ir	n.a.	n.a.
Führung 042515541TD0302FUHRFL	Ir	n.a.	n.a.
Führung, Gigli-Säge 042515541TD0302FUHRGIGL9G	Ir	n.a.	n.a.
Fadenführer 042515541TD0302FADENFUHSS	Ir	n.a.	n.a.
Elevatorium 042515541TD0303ELEVATOR6H	Ir	n.a.	n.a.
Fadeninstrument 042515541TD0303FADENINSTZ	Ir	n.a.	n.a.
Schutzschild 042515541TD0303SCHILDJC	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
Pinzette 042515541TD0303PINZETTEGZ	Ir	n.a.	n.a.
Haken, sonstiges 042515541TD0303HAKENSONZD	Ir	n.a.	n.a.
Schraubendreher, Knochen, Kunststoff 042515541TD0304SCREWKUNDW	Ir	n.a.	n.a.
Extraktor 042515541TD0304EXTRAKTOH7	Ir	n.a.	n.a.
Meißel 042515541TD0305MEISELKA	Ir	n.a.	n.a.
Dermatom 042515541TD0305DERMATOM5H	Ir	n.a.	n.a.
Sezierer 042515541TD0305SEZIERERG8	Ir	n.a.	n.a.
Messer 042515541TD0305MESSERMU	Ir	n.a.	n.a.
Osteotom 042515541TD0305OSTEOTOMLL	Ir	n.a.	n.a.
Säge, Knochen, manuell 042515541TD0305SAEGEKNO4F	Ir	n.a.	n.a.
Ahle 042515541TD0305AHLED3	Ir	n.a.	n.a.
Dilatator 042515541TD0306DILATATO3K	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
Spreizer 042515541TD0306SPREIZERLA	Ir	n.a.	n.a.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-01-17	D1357900015	Rev 01: Supplemented by class Ir products
2024-03-15	D1357900012	Initial