Gültig bis 29.07.2023
Valid until July 29th, 2023
Gemäß EG-Richtlinie 93/42/EWG von Juni 1993
Acc. MDD 93/42/EEC of June 1993

Wir / *We*

REGER Medizintechnik GmbH
Gewerbestraße 10
D-78667 Villingendorf
Tel.: +49 741 270 698- 0
Fax: +49 741 270 698- 10

erklären in alleiniger Verantwortung, dass unsere Produktgruppen, welche in folgender Tabelle aufgeführt sind unter Beachtung folgender Richtlinien und Normen hergestellt wurden und mit CE 0483 gelabelt werden:

declare on our sole responsibility that our product lines listed in the following table are manufactured under consideration of the following directives and standards and labeled with **CE 0483***:*

DIN EN ISO 13485: 2012-11
EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II ohne Abschnitt 4 vom 14.06.1993

DIN EN ISO 13485: 2012-11
Medical Device Directive 93/42/EEC, Annex II except for Section 4 of June 14th, 1993

Produktgruppe *product*	**Artikelnummer** *article*	**Risikoklasse** *risk- class*	**Regel** *rule*	**UMDNS- Code** *UMDNS- Code*
HF-Handgriffe *HF-handles*	92043 bis 92049, 92096 bis 92098, 92151, 92240 bis 92300, 92443, 92446, 92447, 92644 bis 92649, 92736 bis 92739, 92740 bis 92754,	**IIb**	**9**	**11-499**

	92756, 92757, 92843, 92847, 92889-0 bis 92889-19			
HF-Handgriffe mit Rauchgasabsaugung *HF-handles incl. smoke evacuation*	92650 bis 92652 92660 bis 92662	**IIb**	**9**	**11-499**

Die Produkte werden gemäß den grundlegenden Anforderungen der Richtlinie 93/42/EWG Anhang I hergestellt.

The products are manufactured under the essential requirements of the directive 93/42/EEC annex I.

Adresse der Benannten Stelle/ *Address of Notified Body:*
mdc medical device certification GmbH, Kriegerstraße 6, DE- 70191 Stuttgart

Ort/*City*: Villingendorf

Datum/*Date*: 12.05.2021

Alexander Hetzel. Dipl. Wirt.-Ing. (FH) / MBA
Geschäftsführer/*Managing Director*
REGER Medizintechnik GmbH

REGER Medizintechnik GmbH
Gewerbestraße 10
78667 Villingendorf
Deutschland

Notified Body Confirmation Letter

Reference: D1228500018

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:

REGER Medizintechnik GmbH
Gewerbestraße 10
78667 Villingendorf
Deutschland
SRN: DE-MF-000005910, DE-IM-000017484

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 an 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 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 the 20 Mar 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:

- 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, 2023-09-19

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
Arthroskopie-Elektroden (monopolar und bipolar) steril zum Einmalgebrauch Basic UDI-DI: Monopolar steril: 42506461TD890MS8X Bipolar steril: 42506461TD890BS7W Bipolar steril, Integriertes System: 42506461TD890BFSAP	Class IIb excluding Class IIb implantable non-WET	Arthroskopie-Elektroden (monopolar und bipolar) steril zum Einmalgebrauch	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
Arthroskopie-Elektroden (monopolar und bipolar) unsteril zur Wiederverwendung Basic UDI-DI: Monopolar Unsteril: 42506461TD890MA7T Bipolar Unsteril: 42506461TD890BA6S	Class IIb excluding Class IIb implantable non-WET	Arthroskopie-Elektroden (monopolar und bipolar) unsteril zur Wiederverwendung	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
Arthroskopie-Elektroden (monopolar und bipolar) unsteril zum Einmalgebrauch Basic UDI-DI: Monopolar Unsteril: 42506461TD890MA7T Bipolar Unsteril: 42506461TD890BA6S	Class IIb excluding Class IIb implantable non-WET	Arthroskopie-Elektroden (monopolar und bipolar) unsteril zum Einmalgebrauch	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588

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-Elektroden (Standard-Elektroden monopolar und bipolar) unsteril Basic UDI-DI: Monopolar Standard: 42506461TD400MS5L Monopolar Laparoskopie: 42506461TD400ML56 Bipolar Urologie: 42506461TD400BU4P Bipolar HNO: 42506461TD890BH78	Class IIb excluding Class IIb implantable non-WET	HF-Elektroden (Standard-Elektroden monopolar und bipolar) unsteril	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
HF-Pinzetten bipolar unsteril Basic UDI-DI: Bipolare Pinzetten: 42506461TD950BQ Bipolare Pinzetten SiTec (Antihaft): 42506461TD950SiA2	Class IIb excluding Class IIb implantable non-WET	HF-Pinzetten bipolar unsteril	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
Vernebler steril zum Einmalgebrauch Basic UDI-DI: 42506461TD770S8A	Class IIb excluding Class IIb implantable non-WET	Vernebler steril zum Einmalgebrauch	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
Vernebler unsteril zum Einmalgebrauch Basic UDI-DI: 42506461TD770BL	Class IIb excluding Class IIb implantable non-WET	Vernebler unsteril zum Einmalgebrauch	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588

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-Handgriffe mit Tasten, unsteril Basic UDI-DI: Monopolar: 42506461TD920M7K Bipolar: 42506461TD920B6V Rauchgasabsaugung: 42506461TD920R7V	Class IIb excluding Class IIb implantable non-WET	HF-Handgriffe unsteril	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588
HF-Handgriffe, ohne Tasten, unsteril Basic UDI-DI: Monopolar: 42506461TD920M7K Bipolar: 42506461TD920B6V Rauchgasabsaugung: 42506461TD920R7V	Class IIa	HF-Handgriffe unsteril	MDD Zertifikat Registrier Nr. D1228500014 Bericht Nr. P20-01831-190588

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-09-19	D1228500018	Initial