REGER Medizintechnik GmbH Gewerbestrasse 10 D 78667 Villingendorf

To whom it may concern:

REGER Medizintechnik GmbH
Gewerbestrasse 10
D 78667 Villingendorf
Telefon (0741) 270 698-0
Telefax (0741) 270 698-10
www.reger-med.de
info@reger-med.de

23. August 2023

Ref: Amendment to Declarations of Conformity

We, the legal manufacturer, REGER Medizintechnik GmbH, herewith affirm, that the following product groups are subjected to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.
REGER Medizintechnik GmbH complies with the specifications set forth in Regulation (EU) 2023/607 for the following product groups.

For these products the extension period until 31st Dec 2028 already applies:

Product category	Product	Class	Product Code
Instruments and accessories for electrosurgery	HF-Handles (controllable)	IIb	11-499
	HF-Handles (non-controllable)	IIa	11-499
	Bipolar Forceps	IIb	11-502
	HF-Electrodes, monopolar and bipolar, non-sterile	IIb	15-579
	HF-Electrodes, monopolar and bipolar, sterile	IIb	15-579
Instruments and accessories for surgery	Nebulizer Sterile and non-sterile for single use	IIa	12-712

The aforementioned MDD products are under surveillance of our Notified Body, mdc Stuttgart, and have been surveyed actually again on 27.-28. June 2023. The MDR Tech Files for these products have been submitted to our Notified Body for review and the MDR contract has been concluded.

We hope that this information will be useful for you.

Yours faithfully

REGER Medizintechnik GmbH
Alexander Hetzel
Managing Director / CEO

Geschäftsführer / CEO: Alexander Hetzel – Registered Court: Amtsgericht Stuttgart HRB 471153 – Steuernummer / Tax ID: 19060/0775 -
www.reger-med.de

Gültig bis 2023-07-29
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
78667 Villingendorf
Germany
Tel +49 741 270 698 - 0
Fax +49 741 270 698 – 10

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

declare on our sole responsibility that our medical products, listed in the table below, are manufactured under consideration of the following directives and standards and are labelled with CE 0483*:*

DIN EN ISO 13485:2016
EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II ohne Abschnitt 4 vom 14.06.1993

DIN EN ISO 13485:2016
Medical Device Directive 93/42/EEC, Annex II except for Section 4 of June 14th, 1993

Produktgruppe / Produktliste *Product Group / Device List*	**Risikoklasse** *Risk Class*	**Regel** *rule*	**UMDNS Code** *UMDNS Code*
HF-Elektroden *HF-Elektrodes* **Artikel Nr. / *Article No.*** 100-0 - 253-9 255-0 - 691-0 700-0 - 769-0 784-0 800-1 - 836-1 9600x	**IIb**	**9**	**15-579**

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*: 14.05.2021

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