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