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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
014101	713338818	medical_devices@tuvsud.com	---	2024-09-20	1 of 7

TÜV SÜD Product Service GmbH Confirmation Letter

CL 014101 0002 Rev. 00

Reference: 713338818

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000013583

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below:

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

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If 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL_014101_0002_Rev_00

In case of inquiries please contact: medical_devices@tuvsud.com

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-20

TÜV SÜD Product Service GmbH
Medical and Health Services


Sonja Töppen (20. September 2024 12:11 GMT+2)

Sonja Töppen
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services


Maria Rosaria Palminteri (20. September 2024 12:46 GMT+2)

Maria Rosaria Palminteri
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
<p>Basic UDI-DI: 426237454ELEKT8E</p> <p>Models:</p> <ul style="list-style-type: none"> • Multi-Tip Feindraht-Elektrode Nr. 41 • Nadel-Elektrode Nr. 6 • Nadel-Elektrode Nr. 2 • Beschichtete Nadel-Elektrode Nr. 2 • Schlingen-Elektrode Nr. 15 • Runde Schlingen-Elektrode Nr. 44 • Runde Schlingen-Elektrode Nr. 24 • Runde Schlingen-Elektrode Nr. 43 • Rauten-Elektrode Nr. 53 • Rauten-Elektrode Nr. 45 • Dreieck-Elektrode Nr. 46 • Dreieck-Elektrode Nr. 26 • Starre Nadel-Elektrode Nr. 37 • Starre Nadel-Elektrode Nr. 38 • Starre Nadel-Elektrode Nr. 39 • Kurze Blatt-Elektrode Nr. 05 • Lange Blatt-Elektrode Nr. 10 • Kugel-Elektrode Nr. 48 • Kugel-Elektrode Nr. 49 • Starre, dicke Nadel-Elektrode Nr. 47 • Kugel-Elektrode Nr. 51 • Beschichtete Parazentese-Elektrode Nr. 97 • Bajonettförmige HNO-Elektrode Nr. 52 • Abgewinkelte Concha-Elektrode Nr. 40 • Spezial-Elektrode Nr. 50 • Feindraht-Elektrode Nr. 42 • HNO-Nadel-Elektrode Nr. 32 • HNO-Schlingen-Elektrode Nr. 35 • HNO-Kugel-Elektrode Nr. 34 • HNO-Nadel-Elektrode Nr. 36 • Bipolare Stich-Elektrode, hinten abgewinkelt • Bipolare Stich-Elektrode, vorne abgewinkelt • Kugel-Elektrode groß • Kugel-Elektrode klein • Nadel-Elektrode stumpf • Kegell-Elektrode • Platten-Elektrode • Kleine Disc-Elektrode Nr. 80 • Große Disc-Elektrode Nr. 85 • Beschichtete Feindraht-Elektrode Nr. 55 • Beschichtete Feindraht-Elektrode Nr. 56 • Unbeschichtete Skerotherapie-Elektrode Nr. 09 • Unbeschichtete Skerotherapie-Elektrode Nr. 10 • Unbeschichtete Skerotherapie-Elektrode Nr. 11 • Beschichtete, gebogene Nadel-Elektrode Nr. 63 • ultrafeine Schneideelektrode gerade, 1 Stück • ultrafeine Schneideelektrode gerade, 2 Stück • ultrafeine Schneideelektrode gerade, 5 Stück • ultrafeine Schneideelektrode abgewinkelt, 1 Stück • ultrafeine Schneideelektrode abgewinkelt, 2 Stück • ultrafeine Schneideelektrode abgewinkelt, 5 Stück 	<p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p>	<p><input checked="" type="checkbox"/> N/A</p>	<p><input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT)</p> <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<ul style="list-style-type: none"> • Spezial-Elektroden Gynäkologie Schlinge 17 x 15 mm • Spezial-Elektroden Gynäkologie Schlinge 10 x 10 mm • Spezial-Elektroden Gynäkologie Schlinge 15 x 15 mm • Spezial-Elektroden Gynäkologie Schlinge 20 x 15 mm • Schneide-Elektrode Drahtlänge 2,5 mm • Schneide-Elektrode Drahtlänge 12 mm • Schneide-Elektrode Drahtlänge 25 mm • Disc-Elektroden-Satz • Standard-Elektroden-Satz Nr. 300 • HNO-Elektroden-Satz • Starre Nadel-Elektroden Satz • Sklerotherapie-Elektroden-Satz • Feinstdraht-Elektroden-Satz • BIO-CONE Elektroden klein/flach • BIO-CONE Elektroden klein/medium • BIO-CONE Elektroden klein/tief • BIO-CONE Elektroden medium/flach • BIO-CONE Elektroden medium/medium • BIO-CONE Elektroden medium/tief • BIO-CONE Elektroden groß/flach • BIO-CONE Elektroden groß/medium • BIO-CONE Elektroden groß/tief 			
<p>Basic UDI-DI: 426237454PINZEDE</p> <p>Models:</p> <ul style="list-style-type: none"> • Bipolar-Pinzette Kurz, gerade. Breite der Spitze 0,5 mm • Bipolar-Pinzette Kurz, gerade. Nadelspitze • Bipolar-Pinzette Kurz, gerade. Breite der Spitze 0,5 mm abgewinkelt • Bipolar-Pinzette Kurz, gerade. Nadelspitze abgewinkelt • Bipolar-Pinzette 160 mm lang, gerade. Breite der Spitze 2 mm • Bipolar-Pinzette 160 mm lang, gerade. Nadelspitze • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 1 mm • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 2 mm • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 2 mm (geriffelt) • Bipolar-Pinzette 220 mm lang, gerade. Breite der Spitze 1 mm • Bipolar-Pinzette 220 mm lang, gerade. Breite der Spitze 2 mm • Bipolar-Pinzette 160 mm lang, gerade. Breite der Spitze 0,5 mm abgewinkelt • Bipolar-Pinzette 160 mm lang, gerade. Nadelspitze • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 1 mm abgewinkelt • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 2 mm abgewinkelt • Bipolar-Pinzette 220 mm lang, gerade. Breite der Spitze 1 mm abgewinkelt 	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT) <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
<ul style="list-style-type: none"> • Bipolar-Pinzette 165 mm lang, bajonettförmig. Breite der Spitze 1 mm • Bipolar-Pinzette 195 mm lang, bajonettförmig. Breite der Spitze 1 mm • Bipolar-Pinzette 195 mm lang, bajonettförmig. Breite der Spitze 2 mm • Bipolar-Pinzette 220 mm lang, bajonettförmig. Breite der Spitze 0,5 mm • Bipolar-Pinzette 195 mm lang, bajonettförmig. Breite der Spitze 1 mm nach oben abgewinkelt • Bipolar-Pinzette 220 mm lang, bajonettförmig. Breite der Spitze 1 mm nach oben abgewinkelt • Antihaft-Bipolarpinzette 110 mm lang, gerade. Länge der Spitze 6 mm, Breite 0,5 mm • Antihaft-Bipolarpinzette 160 mm lang, gerade. Länge der Spitze 8 mm, Breite 1 mm • Antihaft-Bipolarpinzette 160 mm lang, gerade. Länge der Spitze 8 mm, Breite 2 mm • Antihaft-Bipolarpinzette 195 mm lang, gerade. Länge der Spitze 8 mm, Breite 1 mm • Antihaft-Bipolarpinzette 195 mm lang, gerade. Länge der Spitze 8 mm, Breite 2 mm • Antihaft-Bipolarpinzette 220 mm lang, gerade. Länge der Spitze 8 mm, Breite 2 mm • Antihaft-Bipolarpinzette 160 mm lang, abgewinkelt. Länge der Spitze 6 mm, Breite 1 mm • Antihaft-Bipolarpinzette 195 mm lang, abgewinkelt. Länge der Spitze 8 mm, Breite 1 mm • Antihaft-Bipolarpinzette 195 mm lang, abgewinkelt. Länge der Spitze 8 mm, Breite 2 mm • Antihaft-Bipolarpinzette 195 mm lang, bajonettförmig. Länge der Spitze 6 mm, Breite 1 mm • Antihaft-Bipolarpinzette 220 mm lang, bajonettförmig. Länge der Spitze 6 mm, Breite 2 mm abgewinkelt • Bipolar-Pinzette 160 mm lang, gerade. Breite der Spitze 1 mm • Bipolar-Pinzette 160 mm lang, gerade. Breite der Spitze 1 mm abgewinkelt • Bipolar-Pinzette 195 mm lang, gerade. Breite der Spitze 2mm (geriffelt) abgewinkelt 			
<p>Basic UDI-DI: 426237454FUSSDJ</p> <p>Models:</p> <ul style="list-style-type: none"> • Fußschalter für HF-Geräte, Kabel 3 m • Multifunktionsfußschalter für HF-Geräte 	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT) <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during applica- tion review)	If the MDR device is a substitute device, identifi- cation of the corresponding- MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p>Basic UDI-DI: 426237454KABEL6J</p> <p>Models:</p> <ul style="list-style-type: none"> • Bipolarkabel • Kabel für selbstklebende Neutralelektrode 	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT) <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>
<p>Basic UDI-DI: 426237454INSTRD5</p> <p>Models:</p> <ul style="list-style-type: none"> • Handstück zum Schneiden für radioSURG@2200 mit gelbem Knopf • Handstück zum Koagulieren für radioSURG@2200 mit blauem Knopf • Handstücke ohne Auslöseknopf 3 m Kabel 	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT) <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>
<p>Basic UDI-DI: 426237454EPIGLUBV</p> <p>Models:</p> <ul style="list-style-type: none"> • EPIGLU® Phiolen (EPIGLUBP) • EPIGLU® Phiolen (EPIGLU1P) • EPIGLU® Phiolen (EPIGLU2P) • EPIGLU® Phiolen (EPIGLU4P) • EPIGLU® Single Dose (EPIGLUSD) • EPIGLU® Single Dose (EPIGLSDF) • EPIGLU® Single Dose (EPIISDP10) • EPIGLU® Single Dose (EPIISDP25) • EPIGLU® Single Dose (EPIISD10F) • EPIGLU® Single Dose (EPIISD25F) • EPIGLU® Phiolen (EPIGLUSP) • Truglue® Single Dose (EPIITRUSD) • Truglue® Single Dose (75005) • Truglue® Single Dose (75006) • Truglue® Single Dose (75007) 	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate #: 2879GB410180918 NB# 0482 (MEDCERT) <p>NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-09-26.</p>



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Not applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-09-20	713338818	Initial issue