

TÜV Rheinland LGA Products GmbH • 51105 Köln

Löwenstein Medical SE & Co. KG
Arzbacher Straße 80
56130 Bad Ems
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 28, 2024

Notified Body Confirmation Letter

Reference: LMSE_PLA0_607_2024-02-27, order #1155764

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Löwenstein Medical SE & Co. KG
Arzbacher Straße 80
56130, Bad Ems
Germany
SRN: DE-MF-000006028

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 the NB is also responsible for appropriate surveillance 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body



 Digital
 unterschrieben von
 Karsten Kluge
 Datum: 2024.03.28
 i.V. Dr. K. Kluge 12:03:44 +01'00'
 Certification 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 |
|---|---|--|--|
| Project warmer 426017127IsothermGV | Class IIb non-implantable | Isotherm | HD 60146428 0001 #0197 |
| Project warmer 426017127WarmerInfantYD | Class IIb non-implantable | Lifetherm 2000 | HD 60146428 0001 #0197 |
| Project warmer 426017127WarmerInfantYD | Class IIb non-implantable | Lifetherm 2002 | HD 60146428 0001 #0197 |
| Project warmer 426017127WarmerInfantYD | Class IIb non-implantable | Lifetherm 2003 | HD 60146428 0001 #0197 |
| Sinus, Sinus TR | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leon | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |

| 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 |
|--|--|---|---|
| Leon Wand | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leon MRI | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leoni Plus | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leoni Plus CLAC | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leoni Plus HFO | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leoni Plus HFO CLAC | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| Leoni Plus HFO transport | Class IIb non-implantable | N/A | HD 60146428 0001 #0197 |
| bilibluelight | Class IIa | N/A | HD 60146428 0001 #0197 |
| NeoJet NCPAP Generator | Class IIa | NeoJet 2000 nCPAP | HD 60146428 0001 #0197 |
| NeoJet Prong | Class IIa | NeoJet 2000 nCPAP | HD 60146428 0001 #0197 |
| NeoJet Mask | Class IIa | NeoJet 2000 nCPAP | HD 60146428 0001 #0197 |

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 |
|--|--|---|---|
| N/A | N/A | N/A | N/A |

Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|-------------|--|------------------------------------|
| 2024/03/28 | LMSE_CL607_2024-03-28 | Initial issue |
| YYYY/MM/DD | XXXXXXXXXX | Addition of device XYZ to the list |
| YYYY/MM/DD | XXXXXXXXXX | Removal of device XYZ to the list |