Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Löwenstein Medical Technology GmbH + Co. KG
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Contact

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Date December 14, 2023

Notified Body Confirmation Letter
Reference: LOEWE_PLA_607_2023-12-13, order #1154641

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 Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Germany
SRN Number: DE-MF-000006010

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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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

Dr. K. Kluge

i.V. Dr. Karsten Kluge

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# 0197 Identification**
WM090TD: prisma SOFT prisma SMART prisma SOFT plus prisma SMART plus prisma SOFT max prisma SMART max	Class IIa	N/A	HD 60131384 0001; NB# 0197
WM100TH: prismaAQUA	Class IIa	N/A	HD 60131384 0001; NB# 0197
WM110MS: prisma CHECK	Class IIa	N/A	HD 60131384 0001; NB# 0197
prismaTS: prismaTS prismaTSlab	Class IIa	N/A	HD 60131384 0001; NB# 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# 0197 Identification
JOYCEclinic Full Face: JOYCEclinic Full Face JOYCEclinic Full Face NV + AAV JOYCEclinic Full Face NV	Class IIa	N/A	HD 60131384 0001; NB# 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-14	LOEWE_CL607_2023-12-14	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131384 0001

Report No.: 21196116 018

Manufacturer:
Löwenstein Medical Technology
GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products:
Medical devices for sleep medicine, ventilation,
patient interface and diagnosis
(see attachment for products and sites included)

Replaces EC-Certificate, Registration No.: HD 60129205 0001

Expiry Date: 2023-05-21

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-07-26

Date: 2018-07-26

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131384 0001
Report No.: 21196116 025

Manufacturer: Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products included:

Sleep Diagnostics:
- Sleep Apnea Diagnostic Systems
- Polygraphy
- Polysomnography
- Sleep Diagnostic Software

Sleep Therapy:
- Sleep Apnea Therapy Systems
- Heated Humidifiers
- Breathing Tubes
- Oxygen Valves
- Bacteria Filters
- Sleep Therapy Software

Notified Body

Date: 2020-09-16

Dipl.-Ing. F. Schwingen

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131384 0001
Report No.: 21196116 025

Manufacturer: Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products included:

Ventilation:
- Ventilation Systems
- Heated Humidifiers
- Oxygen Valves
- SpO2 Module
- Ventilation Software

Patient Interface:
- Breathing Masks
- Exhalation Systems
- Nasal/Oral cannulas

Software for configuration and Data Analysis

Site included:
Löwenstein Medical Technology GmbH + Co. KG
Site Karlsruhe
Südendstraße 42, 76135 Karlsruhe, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. F. Schwingen

Date: 2020-09-16