Business Stream Products
Certification Department

TÜVRheinland®
LGA

TÜV Rheinland LGA Products GmbH • 51105 Köln • Germany

Löwenstein Medical Technology GmbH + Co. KG
Dr. Christoph Lemke
Kronsaalsweg 40
22525 Hamburg
Germany

Contact

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Fax +49 221 806-1601

Mail Marc.Engelhardt
@tuv.com

Köln, 25 May 2023

Dear Dr. Lemke,

Thank you for getting back to us in the question on the confirmation of extension of existing MDD certificates bound to expire shortly or already expired after the 20th of March 2023 (date of publication of EU 2023/607 within the European Journal).

In the context of the cited regulation, all MDD certificates that were valid on the 20th of March 2023 are extended until December 2027 resp. 2028 (depending on the risk class of the devices in question) by law. The understanding is that the dates mentioned within the amending regulation override the expiration dates mentioned on the individual certificates. There are certain actions that need to be undertaken by medical device manufacturers and Notified Bodies to allow the extension to be maintained prior to the final expiration dates mentioned within the regulation. A formal extension application for individually listed products by the manufacturers must be filed by the 26th of May 2024. The manufacturer Löwenstein Medical Technology GmbH +Co. KG has implemented a quality management system that complies with MDR requirements since 13th of July 2020 (EU certificate HZ 1010032-1). First product groups legally manufactured by the company have already been certified according to EU 2017/745 (MDR).

The amending regulation does not see the need for a letter from behalf of Notified Bodies to their clients that confirms the validity of certificates expiring between the 20th of March 2023 and the 25th of May 2024, as the validity is already stated within EU 2023/607.

We are aware that the extension of certificates by law is an unusual procedure, especially if an individual certificate expires prior to the 26th of May 2024 (or has already expired but was still valid on the 20th of March 2023). The expectations are nevertheless that this understanding becomes overall consent. In case of any further questions or comments please do not hesitate to contact us.

We appreciate your understanding and your business

Sincerely

i. V.

25. 05. 2023

Marc Engelhardt

Head of Certification Department
TÜV Rheinland LGA Products GmbH

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein 29
51105 Köln
Germany

Headquarter

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LÖWENSTEIN
medical

To whom it may concern

Declaration on Extension of EC Certificate according to (EU) 2023/607 amending (EU) 2017/745

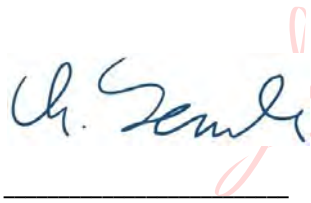
Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40 ▪ 22525 Hamburg ▪ Germany

We hereby declare that our **MDD EC certificate HD 60131384 0001** issued by Notified Body TÜV Rheinland LGA Products GmbH is **valid until 26 May 2024**.

We benefit from the transitional period implemented with Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (Article 120(2), second subparagraph, first sentence) and fulfill the conditions set out in Article 120(3C), points (a) to (c).

The extension of the transitional period and the concomitant extension of the certificate's validity is done automatically by law and the Notified bodies cannot issue new MDD certificates. Hence the expiry date stated on the MDD EC certificate HD 60131384 0001 is invalid.

Therefore, all legacy devices listed on the *Request for update of the MDD certification scope* dated from 28 July 2022 (see attachment) can still be placed on the market until the end of the transitional period 26 May 2024.



Digitally signed by
Christoph Lemke
Date: 2023.03.30
16:52:37 +02'00'

Dr. Christoph Lemke
CQO, Director Quality and Regulatory Affairs
Löwenstein Medical Technology GmbH + Co. KG

With people in mind

Request for update of the MDD certification scope

TÜVRheinland®

Name of Legal Manufacturer:	Löwenstein Medical Technology GmbH + Co. KG
Address of Legal Manufacturer:	Kronsaalsweg 40 22525 Hamburg Germany
MDD 93/42/EEC	Annex II excluding section 4
EC Certificate number	HD 60131384 0001
Reason for submission:	Other changes

DECLARATION OF THE LEGAL MANUFACTURER

I hereby declare that the requested planned update of the MDD certification scope will be conducted in full compliance with the requirements of the EC Directive 93/42/EC.

This document is intended to amend information related to facilities and/or products listed on current valid "Product List and Application MDD, AIMD", approved by TÜV Rheinland LGA Products GmbH.
I hereby declare that the requirements of EU Regulation 2017/745 (MDR), Article 120 (3) with the derived MDR requirements are fulfilled.
All declarations signed by the legal manufacturer on valid and approved "Product List and Application MDD, AIMD" application documents remain unchanged.

Please provide the signed version of this document and the related Excel file to your TÜV Rheinland contact.
The document should be submitted with a (Significant) Change Notification (MS-0036869).

Request for update of the MDD certification scope

TÜVRheinland®

FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility
EAR(1)	European authorised Representative	not applicable	not applicable
IMF(1)	Internal Manufacturing Facility	Löwenstein Medical Technology GmbH + Co. KG	Kronsaalsweg 40 22525 Hamburg Germany
EMF(1)	External Manufacturing Facility	Kleinmontagen Wiechmann GmbH	Heideweg 5-7 19300 Grabow Germany
EMF(2)	External Manufacturing Facility	Benchmark Electronics Romania SRL	Strada Hermann Oberth nr. 23 Parcul Industrial ICCO, Hala H3 Localitate Ghimbav 507075 Jud Brasov, Romania
EMF(3)	External Manufacturing Facility	not applicable	not applicable
EMF(4)	External Manufacturing Facility	Löwenstein Medical SE & Co. KG	Kreuzwiese 7 56337 Simmern Germany
EMF(5)	External Manufacturing Facility	seleon gmbh	Brauereistraße 13 06847 Dessau Deutschland
EMF(6)	External Manufacturing Facility	Hecht + Dieper Präzisionsspritzguss GmbH	Gerberstr. 9 51789 Lindlar Germany
R&D(1)	Research & Development	Löwenstein Medical Technology GmbH + Co. KG	Kronsaalsweg 40 22525 Hamburg Germany

Request for update of the MDD certification scope

TÜVRheinland®

R&D(2)	Research & Development	Löwenstein Medical Technology GmbH + Co. KG, Niederlassung Karlsruhe	Südendstrasse 42 76135 Karlsruhe Germany
OEM(1)	Original Equipment Manufacturer	not applicable	not applicable
S_RAD(1)	Sterilization facility Radiation - Please select method	not applicable	not applicable
S_GAS(1)	Sterilization facility Gas - Please select method	not applicable	not applicable
S_HEAT(1)	Sterilization facility Heat - Please select method	not applicable	not applicable
S_OTH(1)	Sterilization facility Other : Please specify	not applicable	not applicable

Please add lines as required!

Note: To add line, please select and copy entire corresponding row, and insert copied cells.

Request for update of the MDD certification scope

TÜVRheinland®

PRODUCTS:

Note: Please list all devices covered by the certification.

No.	Product name (as listed on label)	General product group name	Classification of product and classification rule resulting in highest risk class		Allocation of all products into Device Subcategory [NBOG BPG 2009-3]	Allocation of class IIb products		TD/DD identifier	Summary list of related facilities (use facility codes from Facilities table, i.e IMF(1), IR&D(1))	Code of EU-REP (use facility No from Facilities table)
			Classification Rule including subclause according to Annex IX	Device Class		Generic Device Group Name (= GMDN term name)	GMDN code			
1	Silentflow 2	keine Bezeichnung	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2208	R&D(1);EMF(1);	
2	SOMNOclick 300	Befeuchter, beheizt	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2293	R&D(1);EMF(1);	
3	JOYCE vented / JOYCE non-vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2293	R&D(1);EMF(1);	

4	SOMNOaqua	Befeuchter, beheizt	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2236	R&D(1);IMF(1);	
5	SOMNOcheck micro	Apnoe Monitor	10	IIa	MD 1302 Monitoring devices of vital physiological parameters			2346	R&D(2);IMF(1);	
6	SOMNObalance / SOMNObalance e	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2312	R&D(2);EMF(2);	
7	JOYCE Full Face vented / JOYCE Full Face non-vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2283	R&D(1);EMF(1);	
8	JOYCE Full Face plus vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2379	R&D(1);EMF(1);	
9	SOMNOcheck micro CARDIO	Apnoe Monitor	10	IIa	MD 1302 Monitoring devices of vital physiological parameters			2431	R&D(2);IMF(1);	

10	VENTIlogic LS	Beatmungsgerät	11	IIb	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	portable electric ventilator	47083	007 (2328)	R&D(1);IMF(1);EMF(5)	
11	Silentflow 3	keine Bezeichnung	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			422	R&D(1);EMF(6)	
12	LUISA (LM150TD)	Beatmungsgerät	11	IIb	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	portable electric ventilator	47083	005	R&D(1);IMF(1);	
13	TIVAN 30 (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003	R&D(1);R&D(2);IMF(1);	

14	TIVAN 40 (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003	R&D(1);R&D(2);IMF(1);	
15	TIVAN 50 (WM120TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			004	R&D(1);R&D(2);IMF(1);	
16	TIVAN 30-C (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003	R&D(1);R&D(2);IMF(1);	
17	prisma Comfort40 (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003	R&D(1);R&D(2);IMF(1);	

18	NP 15	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			213 (2394)	R&D(1);EMF(1);	
19	OXYnasor supra	Nasal-/Oralbrille	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			215 (2511)	R&D(1);EMF(4);	
20	JOYCE SilkGel NM vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			209 (2392)	R&D(1);EMF(1);	
21	JOYCE SilkGel FFM vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			210 (2392)	R&D(1);EMF(1);	
22	SOMNOsoft 2 / SOMNOsoft 2 e	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2405	R&D(2);EMF(2);	
23	JOYCEeasy vented Nasal	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			203 (2391)	R&D(1);IMF(1);EMF(1);EMF(4);	
24	JOYCEeasy vented FFM / JOYCEeasy FFM NV	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			204 (2438)	R&D(1);EMF(1);	

25	SOMNOlab-Software	Polygrafie- und Polysomnografie-Software	10	IIa	MD 1111 Software			419 (2448)	R&D(2);IMF(1);	
26	VENTIclick	Befeuchter, beheizt	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2289 18.05.2005	R&D(1);IMF(1);	
27	JOYCEone vented NM	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			205 (2454)	R&D(1);EMF(1);EMF(4);	
28	JOYCEeasy X / JOYCEeasy X Full Face	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2485	R&D(1);EMF(1);	
29	prisma VENT50-C (WM120TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			004 26.04.2018	R&D(1);R&D(2);IMF(1)	
30	JOYCE Lite Full Face vented / JOYCE Lite Full Face non-vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2441	R&D(1);EMF(1);	

31	prismaLAB (WM100TD)	CPAP-Beatmungseinheit (Titrationsgerät)	11	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			002 (2395)	R&D(1);R&D(2);IMF(1);	
32	prismaTS / prismaTSlab	Compliance-und Titrationssoftware	11	IIa	MD 1111 Software			406 (2472)	R&D(2);IMF(1);	
33	JOYCEone vented FFM / JOYCEone FFM NV	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			206 (2471)	R&D(1);EMF(1);EMF(4);	
34	prisma SOFT plus (WM090TD)	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001	R&D(2);EMF(2);IMF(1)	
35	prisma SOFT max (WM090TD)	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001	R&D(2);EMF(2);IMF(1)	
36	Faltenschlauch desinfizierbar	Atemschlauch	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2921	R&D(1);EMF(1);	

37	CARA Full Face	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			202 (2507)	R&D(1);EMF(4)	
38	prisma SMART plus (WM090TD)	APAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001	R&D(2);EMF(2); IMF(1)	
39	prisma SMART max (WM090TD)	APAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001	R&D(2);EMF(2); IMF(1)	
40	prisma20C (WM100TD)	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	

41	prisma20A (WM100TD)	APAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	
42	prismaCR (WM100TD)	Server-Ventilation-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	
43	prisma25S (WM100TD)	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	
44	prisma25ST (WM100TD	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	

45	prisma25S-C (WM100TD)	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	
46	prisma30ST (WM100TD)	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2395)	R&D(1);R&D(2);IMF(1);	
47	oMnia	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2961	R&D(1);EMF(1);	
48	oMnia Full Face	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2961	R&D(1);EMF(1);	
49	TIVAN (WM100TD)	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002 (2961)	R&D(1); R&D(2); IMF(1);	

50	prismaAQUA (WM100TH)	Befeuchter, beheizt	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			401 (2961)	R&D(1); R&D(2);IMF(1);EMF(1),EMF(4);	
51	JOYCEclinic FF vented / JOYCEclinic FF NV / JOYCEclinic FF NV + AAV	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			208 (2493)	R&D(1);EMF(4);	
52	prisma CHECK (WM110MS)	SpO2 Modul	10	IIa	MD 1302 Monitoring devices of vital physiological parameters			402 (2477)	R&D(1);R&D(2);IMF(1);	
53	JOYCEeasy next FFM vented / JOYCEeasy next FFM non vented	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			207 (2494)	R&D(1);EMF(1);EMF(4);	
54	prisma SOFT (WM090TD)	CPAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001 (2489)	R&D(2);EMF(2); IMF(1)	

55	prisma SMART (WM090TD)	APAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			001 (2489)	R&D(2);EMF(2); IMF(1)	
56	prisma VENT30 (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003 (2464)	R&D(1);R&D(2); IMF(1);	
57	prisma VENT30-C (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003 (2464)	R&D(1);R&D(2); IMF(1);	
58	prisma VENT40 (WM110TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			003 (2464)	R&D(1);R&D(2); IMF(1);	

59	JOYCEeasy comfort nasal / JOYCEeasy comfort FFM	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2391	R&D(1);EMF(1);	
60	Intensa FFM vented / Intensa FFM, NV /Intensa FFM NV + AAV	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2493	R&D(1);EMF(4);	
61	prisma VENT50 (WM120TD)	Beatmungsgerät	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			004 (2495)	R&D(1);R&D(2);IMF(1);	
62	CARA	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			201 (2503)	R&D(1); EMF(1); EMF(4);	
63	Endoskopieadapter non-vented	Endoskopieadapter	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			2449	R&D(1); IMF(1)	
64	prisma CLOUD	Web-based system for data analysis of Löwenstein Medical therapy devices	11	IIa	MD 1111 Software			407	R&D(2);IMF(1);	

Request for update of the MDD certification scope

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65	prisma30ST-HFT (WM100TD)	BiLevel-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			002	R&D(1);R&D(2);IMF(1);	
66										

Please add or delete lines as required!

Hamburg	28.07.2022	
Location	Date	Legally binding signature

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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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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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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

Date: 2020-09-16

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. F. Schwingen

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Doc. 2/2, 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:

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