

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


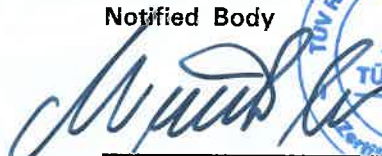
Expiry Date: 2023-05-21

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60131384 0001
Report No.: 21196116 018

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

Products included:

Sleep Diagnostics:


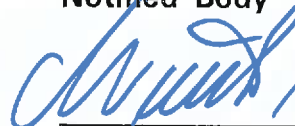
- Sleep Apnea Diagnostic Systems
- Polygraphy
- Polysomnography
- Sleep Diagnostic Software

Sleep Therapy:

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

Date: 2018-07-26

Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60131384 0001
Report No.: 21196116 018

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:


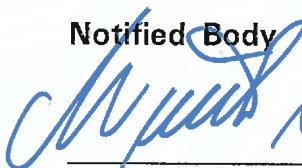
- Breathing Masks
- Exhalation Systems

Site included:

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

Date: 2018-07-26

Notified Body



Dipl.-Ing. I. Munkler

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

Request for update of the MDD certification scope



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.

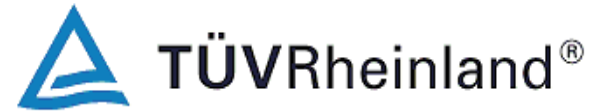
This document is intended to amend information related to facilities and/or products listed on current valid "Product List and Application MDD, AIMD", approved by TÜV Rheinland LGA Products GmbH.

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).***

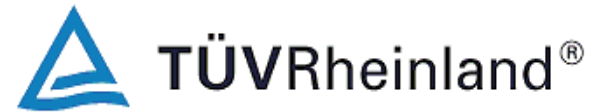
Request for update of the
MDD certification scope



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



R&D(2)	Research & Development	Löwenstein Medical Technology GmbH + Co. KG, Niederlassung Karlsruhe	Südenstrasse 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

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

Request for update of the MDD certification scope



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);	

Request for update of the
MDD certification scope



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);

Request for update of the
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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);E MF(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);I MF(1);	

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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);I MF(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);I MF(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);I MF(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);I MF(1);

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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);E MF(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);	

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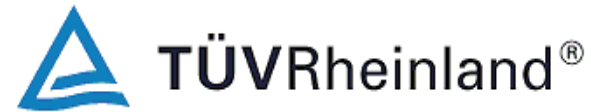
25	SOMNOlab-Software	Polygrafie- und Polysomnografie-Software	10	IIa	MD 1111 Software			419 (2448)	R&D(2);IMF(1);	
26	VENTiclick	Befeuchter, beheizt	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			2289 18.05.2005	R&D(1);IMF(1);	
27	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);	

Request for update of the MDD certification scope



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);	

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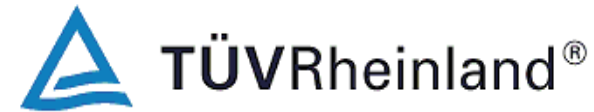
37	CARA Full Face	Maske	2	IIa	MD 0101 Non-active devices for anaesthesia, emergency and intensive care			202 (2507)	R&D(1);EMF(4)	
38	prisma SMART plus (WM090TD)	APAP-Beatmungseinheit	11	IIa	MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			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);I MF(1);	

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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);I MF(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);I MF(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);I MF(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);I MF(1);	

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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);I MF(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);I MF(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);	

Request for update of the
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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);E MF(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);I MF(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);E MF(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)	

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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);	

Request for update of the MDD certification scope



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);

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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);I MF(1);	
66										

Please add or delete lines as required!

Hamburg

Location

28.07.2022

Date

Ch. Lemke
Digitally signed by Christoph
Lemke
Date: 2022.07.28 17:26:15 +02'00'

Legally binding signature