EU-Konformitätserklärung für Medizinprodukte

Wir, der Hersteller, erklären in alleiniger Verantwortung, dass das unten aufgeführte Produkt der Verordnung (EU) 2017/745 und einschlägigen Rechtsvorschriften der Union entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen Endprüfprotokoll.

Hersteller:	Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40, 22525 Hamburg Deutschland
Registrierungsnummer (SRN):	DE-MF-000006010
Basis-UDI-DI:	4050384298186
Produktbezeichnung:	**Beatmungsgerät**
Produktname / Modell:	WM110TD mit den Varianten prisma VENT30, prisma VENT30-C, prisma VENT40, prisma VENT40-C, TIVAN 30, TIVAN 30-C, TIVAN 40, prisma Comfort40, WM100TH als prismaAQUA
Artikelnummer:	29310, 29330, 29510, 29520, 29530, 29540, 29580, 29590, 29520WM0, 29510WM0, 29540WM0, 29530WM0, 29330WM0, 29310WM0, 29310LM0, 29530LM0, 29510LM0, 29330BR0, 29540BR0, 29520BR0, 29310LD0, 29330LD0, 29510LD0, 29520LD0, 29530LD0, 29540LD0, 29330LBR0, 29540LBR0, 29520LBR0, 29510FD0, 29520FD0, 29300-1110, 29300-1111, 29350-1110, 29350-1111, 29360-1110, 29360-1111, 29370-1110, 29370-1111, 29500-1110, 29500-1111, 29550-1110, 29550-1111, 29300HL-4110, 29350HL-4110, 29500HL-4110, 29550HL-4110, 29550WM-1110, 29550WM-1111, 29500WM-1110, 29500WM-1111, 29370WM-1110, 29370WM-1111, 29360WM-1110, 29360WM-1111, 29350WM-1110, 29350WM-1111, 29300WM-1110, 29300WM-1111, 29350BR-1110, 29370BR-1110, 29550BR-1110, 29300LD-1110, 29350LD-1110, 29360LD-1110, 29370LD-1110, 29500LD-1110, 29550LD-1110, 29500FD-1110, 29550FD-1110, 29350LBR-1110, 29370LBR-1110, 29550LBR-1110, 29500MDA-1110, 29550MDA-1110, 29490, 29495, 29490HL0, 29495HL0, 29490FD0, 29560-1110, 29570-1110
Konformitätsbewertungs-verfahren:	Verordnung (EU) 2017/745 über Medizinprodukte Anhang IX, ohne Kapitel II
Klassifizierung:	IIa, nach Anhang VIII der Verordnung (EU) 2017/745
Kennzeichnung:	TÜV-Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Deutschland CE 0197
Zertifikatsnummer:	HZ 1010032-1

Hamburg, den 08.07.2021

ppa. Thomas Weber
CQO, Director Quality and Regulatory Affairs

LÖWENSTEIN medical

WM 74620 07/2021

EU Declaration of Conformity on Medical Devices

We, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity with the regulation (EU) 2017/745 and respective legislations of the union, which apply to it. The declaration is valid in connection with the final inspection report of the device.

Manufacturer:	Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40, 22525 Hamburg Germany
Single Registration Number (SRN):	DE-MF-000006010
Basic UDI-DI:	4050384298186
Product Description:	**Ventilation device**
Product Name / Model:	WM110TD including the variants prisma VENT30, prisma VENT30-C, prisma VENT40, prisma VENT40-C, TIVAN 30, TIVAN 30-C, TIVAN 40, prisma Comfort40, WM100TH as prismaAQUA
Article Number:	29310, 29330, 29510, 29520, 29530, 29540, 29580, 29590, 29520WM0, 29510WM0, 29540WM0, 29530WM0, 29330WM0, 29310WM0, 29310LM0, 29530LM0, 29510LM0, 29330BR0, 29540BR0, 29520BR0, 29310LD0, 29330LD0, 29510LD0, 29520LD0, 29530LD0, 29540LD0, 29330LBR0, 29540LBR0, 29520LBR0, 29510FD0, 29520FD0, 29300-1110, 29300-1111, 29350-1110, 29350-1111, 29360-1110, 29360-1111, 29370-1110, 29370-1111, 29500-1110, 29500-1111, 29550-1110, 29550-1111, 29300HL-4110, 29350HL-4110, 29500HL-4110, 29550HL-4110, 29550WM-1110, 29550WM-1111, 29500WM-1110, 29500WM-1111, 29370WM-1110, 29370WM-1111, 29360WM-1110, 29360WM-1111, 29350WM-1110, 29350WM-1111, 29300WM-1110, 29300WM-1111, 29350BR-1110, 29370BR-1110, 29550BR-1110, 29300LD-1110, 29350LD-1110, 29360LD-1110, 29370LD-1110, 29500LD-1110, 29550LD-1110, 29500FD-1110, 29550FD-1110, 29350LBR-1110, 29370LBR-1110, 29550LBR-1110, 29500MDA-1110, 29550MDA-1110, 29490, 29495, 29490HL0, 29495HL0, 29490FD0, 29560-1110, 29570-1110
Conformity Assessment Route:	Regulation (EU) 2017/745 on medical devices Annex IX, excluding chapter II
Classification:	IIa, according to annex VIII of regulation (EU) 2017/745
Marking:	TÜV-Rheinland LGA Products GmbH Tillystraße 2, 90431 Nuremberg Germany CE 0197
Certificate No.:	HZ 1010032-1

Hamburg, 08/07/2021

ppa. Thomas Weber
CQO, Director Quality and Regulatory Affairs

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