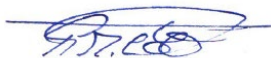


EU-Konformitätserklärung für Medizinprodukte

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: Produktname / Modell:	Beatmungsgerät 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, 29490HLO, 29495HLO, 29490FD0, 29560-1110, 29570-1110
Konformitätsbewertungs- verfahren:	Verordnung (EU) 2017/745 über Medizinprodukte An- hang IX, ohne Kapitel II
Klassifizierung:	Ila, 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

EU Declaration of Conformity on Medical Devices

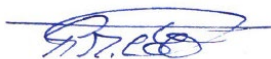
We, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity with the regulation (EU) 2017/745 and respective legislations of the union, which apply to it. The declaration is valid in connection with the final inspection report of the device.

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: Product Name / Model:	Ventilation device 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, 29490HLO, 29495HLO, 29490FD0, 29560-1110, 29570-1110
Conformity Assessment Route:	Regulation (EU) 2017/745 on medical devices Annex IX, excluding chapter II
Classification:	Ila, 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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