

# EU-Konformitätserklärung für Medizinprodukte

Wir, der Hersteller, erklären in alleiniger Verantwortung, dass das unten aufgeführte Produkt den einschlägigen Bestimmungen der nachstehenden Richtlinien und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen Endprüfprotokoll.

Hersteller:	Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40, 22525 Hamburg Deutschland
Produktbezeichnung:	<b>Therapiesystem zur Behandlung schlafbezogener Atmungsstörungen</b>
Produktname / Modell:	<b>WM100TD mit den Varianten prisma20C, prisma20A, prismaCR, prisma25S, prisma25S-C, prisma25ST, prisma30ST, prisma30ST-HFT, pris- maLAB, TIVAN WM100TH als prismaAQUA</b>
Artikelnummer:	WM 29605, WM 29732, WM 29905, WM 29906, WM 29925, WM 29935, WM 29936, WM 29965, WM 29985, WM 29605HLO, WM 29905HLO, WM 29906HLO, WM 29925HLO, WM 29935HLO, WM 29936HLO, WM 29965HLO, WM 29985HLO, WM 29605CN0, WM 29905CN0, WM 29906CN0, WM 29935CN0, WM 29936CN0, WM 29965CN0, WM 29936LD0, WM 29605JP1, WM 29905JP1, WM 29965JP1, WM 29605WM0, WM 29906WM0, WM 29925WM0, WM 29935WM0, WM 29936WM0, WM 29965WM0, WM 29985WM0, WM 29605VCA0, WM 29605BR0, WM 29935BR0, WM 29905BR0, WM 29925BR0, WM 29936BR0, WM 29732BR0, WM 29600-1110, WM 29600-1111, WM 29600-2110, WM 29600-2111, WM 29630-1110, WM 29630-1111, WM 29630-2110, WM 29630-2111, WM 29730-1110, WM 29900-1110, WM 29900-1111, WM 29900-2110, WM 29900-2111, WM 29910-1110, WM 29910-1111, WM 29920-1110, WM 29920-1111, WM 29920-2110, WM 29920-2111, WM 29930-1110, WM 29930-1111, WM 29930-2110, WM 29930-2111, WM 29960-1110, WM 29960-1111, WM 29960-2110, WM 29960-2111, WM 29980-1511, WM 29995-3511, WM 29996-3510, WM 29996-3511, WM 29997-3511, WM 29998-3510, WM 29998-3511, WM 29600HL-4110, WM 29630HL-4110, WM 29900HL-4110, WM 29910HL-4110, WM 29920HL-4110, WM 29930HL-4110, WM 29960HL-4110, WM 29980HL-4110, WM 29930LD-5110, WM 29930LD-5111, WM 29600CN-2111, WM 29630CN-2111, WM 29900CN-2111, WM 29910CN-2111, WM 29920CN-2111, WM 29930CN-2111, WM 29960CN-2111, WM 29980CN-1511, WM 29995CN-3511, WM 29996CN-3511, WM 29600JP1-2111, WM 29900JP1-2111, WM 29960JP1-2111, WM 29600WM-1110, WM 29600WM-1111, WM 29600WM-2110, WM 29600WM-2111, WM 29630WM-1110, WM 29630WM-2110, WM 29630WM-2111, WM 29900WM-1110, WM 29900WM-1111, WM 29900WM-2110, WM 29900WM-2111, WM 29910WM-1110, WM 29910WM-1111, WM 29920WM-2110, WM 29920WM-2111, WM 29930WM-2110, WM 29930WM-2111, WM 29960WM-2110, WM 29960WM-2111, WM 29980WM-1511,

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Konformitätsbewertungsverfahren:

Richtlinie 93/42/EWG über Medizinprodukte Anhang II, ohne Abschnitt 4

Klassifizierung:

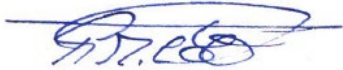
Ila, nach Anhang IX der Richtlinie 93/42/EWG

Kennzeichnung:

TÜV-Rheinland LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg  
Deutschland

**CE 0197**

Hamburg, den 06.07.2021



ppa. Thomas Weber  
CQO, Director Quality and Regulatory Affairs

# EU Declaration of Conformity on Medical Devices

We, the manufacturer, declare in sole responsibility that the product mentioned below is in con-formity with the respective regulations of the following guideline and its transpositions in national laws, 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

Product Description: **Sleep therapy devices and Humidifier**

Product Name / Model: **WM100TD, including the variants prisma20C, prisma20A, prismaCR, prisma25S, prisma25S-C, prisma25ST, prisma30ST, prisma30ST-HFT, prismaLAB, TIVAN WM100TH as prismaAQUA**

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Conformity Assessment  
Route:

Medical Device Directive 93/42/EEC Annex II, excluding section 4

Classification:

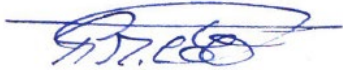
Ila, according to annex IX of directive 93/42/EEC

Marking:

TÜV-Rheinland LGA Products GmbH  
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Germany

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Hamburg, 06/07/2021



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