EC Declaration of Conformity on Medical Devices

We, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity 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:	WM090TD, including the variants prisma SOFT, prisma SMART, prisma SOFT max, prisma SMART max, prisma SOFT plus and prisma SMART plus WM100TH as prismaAQUA
Article Number:	WM 31605, WM 31610, WM 31805, WM 31810, WM 31710, WM 31720, LMT 31730, LMT 31760, WM 31600-1110, WM 31620-1110, WM 31620-1111, WM 31630-1110, WM 31650-1110, WM 31650-1111, LMT 31909, LMT 31905, LMT 31919, LMT 31915, LMT 31929, LMT 31925, LMT 31939, LMT 31935, LMT 31900-1110, LMT 31920-1110, LMT 31900-4110, LMT 31900-1210, LMT 31920-1210, LMT 31930-1110, LMT 31940-1110, LMT 31930-4110, LMT 31930-1210, LMT 31940-1210, LMT 31950-1110, LMT 31960-1110, LMT 31950-4110, LMT 31950-1210, LMT 31960-1210, LMT 31970-1110, LMT 31980-1110, LMT 31970-4110, LMT 31970-1210, LMT 31980-1210, WM 31605HL0, WM 31610HL0, WM 31600HL-4110, WM 31630HL-4110, WM 31620MM-1110, WM 31650MM-1110, WM 31605WM0, WM 31610WM0, WM 31600WM-1110, WM 31620WM-1110, WM 31600WM-1111, WM 31620WM-1111, WM 31605CN0, WM 31610CN0, WM 31620CN-1110, WM 31620CN-1111, WM 31650CN-1110,WM 31650CN-1111, WM 31605VCA0, WM 31610VCA0, WM 31620VCA-1110, WM 31620VCA-1111, WM 31650VCA-1110, WM 31650VCA-1111, WM 31820-1110, WM 31820-1111, WM 31850-1110, WM 31850-1111, WM 1WFM3771PA0, WM 31601OS-1110 LMT 31920FR-1210, LMT 31960FR-1210, LMT 31795-1110, LMT 31785-1110, LMT 31980CA-1110, LMT 31980CA-1210, LMT 31960CA-1110, LMT 31960CA-1210, LMT 31920SA-1210, LMT 31940SA-1210, LMT 31960SA-1210, LMT 31980SA-1210, LMT 31950VA-1110, LMT 31960VA-1210, LMT 31970VA-1110, LMT 31980VA-1210, LMT 31960AH-1110, LMT 31960AH-1210, LMT 31980AH-1110, LMT 31980AH-1210, WM 29490, WM 29495, WM 29680, WM 29685, WM 29680HL0, WM 29690HL0, WM 29490FD0, WM 29680CN0, WM 29685CN0, WM 29680OA0, WM 29685OA0, WM 29490OA0

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Conformity Assessment Route:	Medical Device Directive 93/42/EEC Annex II, excluding section 4
Classification:	IIa, according to annex IX of directive 93/42/EEC
Marking:	TÜV-Rheinland LGA Products GmbH Tillystraße 2, 90431 Nuremberg Germany CE 0197
Certificate No.	HD 60131384 0001

Furthermore, we, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity with the respective regulations of the following guideline:

Product Name / Model:	WM090TD, including the variants prisma SOFT max, prisma SMART max, prisma SOFT plus and prisma SMART plus
Article Number:	LMT 31909, LMT 31905, LMT 31919, LMT 31915, LMT 31929, LMT 31925, LMT 31939, LMT 31935, LMT 31900-1110, LMT 31920-1110, LMT 31900-4110, LMT 31900-1210, LMT 31920-1210, LMT 31930-1110, LMT 31940-1110, LMT 31930-4110, LMT 31930-1210, LMT 31940-1210, LMT 31950-1110, LMT 31960-1110, LMT 31950-4110, LMT 31950-1210, LMT 31960-1210, LMT 31970-1110, LMT 31980-1110, LMT 31970-4110, LMT 31970-1210, LMT 31980-1210
Conformity Assessment Route:	Richtlinie 2014/53/EU (RED) über die Bereitstellung von Funkanlagen auf dem Markt gemäß Anhang II auf Grundlage folgender Normen: IEC 60601-1 :2005+A1: 2012 EN ISO 14971:2012 DIN EN 62311:2008-09 EN 301 489-17 V3.2.0 Draft: 2017 zusammen mit EN 301 489-1 V2.2.0 Draft: 2017 Draft EN 301 489-52 V1.1.0: 2016 zusammen mit EN 301 489-1 V2.1.1: 2017 EN 301 511 V12.5.0, V12.5.1 03-2017 EN 301 908-13 V13.1.1 11-2019 ETSE EN 300 328 V2.2.2 : 2019-07

Hamburg, 27/06/2023

Digitally signed by Christoph Lemke
Date: 2023.06.27 17:57:56 +02'00'

i.V. Dr. Christoph Lemke
CQO, Director Quality and Regulatory Affairs

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