

# 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 Kronsaalweg 40, 22525 Hamburg Germany
Product description:	<b>Sleep therapy devices and Humidifier</b>
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 31605HLO, WM 31610HLO, 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  WM 29680, WM 29685, WM 29680HLO, WM 29685HLO, WM 29680CN0, WM 29685CN0, WM 29680OAO, WM 29685OAO
Guideline:	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 Tillystraße 2, 90431 Nuremberg Germany

**CE 0197**



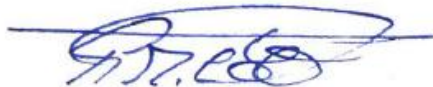
Furthermore, we, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity with the respective regulations of the following guideline:

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

Guideline: Directive 2014/53/EU (RED) relating to the making availa-  
ble on the market of radio equipment Annex II on basis of  
the following standards:  
IEC 60601-1 :2005+A1: 2012  
EN ISO 14971:2012  
DIN EN 62311:2008-09  
EN 301 489-17 V3.2.0 Draft: 2017 in conjunction with  
EN 301 489-1 V2.2.0 Draft: 2017  
Draft EN 301 489-52 V1.1.0: 2016 in conjunction with  
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, 05/01/2021



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CQO, Director Quality and Regulatory Affairs