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EC declaration of conformity

Valid until May 26, 2027

In accordance with Article 19 of Regulation EU-MDR 2017/745 on medical devices of the European Parliament and the Council we explain

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SRN: **DE-MF-000006295**

sole responsibility that the medical device

with the type designation and intended use:
Diagnostic lights

for the items listed below with the basic UDI-DI **426073903RC1970XF**

Product trade name:	**Article no.:**
NOVA	NO100D, NO110D, NO110DW, NO150D, NO160D, NO160DW
LUX	LX200D, LX210D, LX210DW
CE-LIGHT	CE250D, CE260D, CE260DW
LUNA	LU 300D,LU340D
MAGIC	MA350D, MA350DW,MA355D

according to Annex VIII, Paragraph 1, Rule 10 a class I medical device,

conforms to the requirements of EU regulation 2017/745 as well as other relevant legal provisions and fulfills the basic safety and performance requirements according to Annex I of the EU MDR, as well as the specification listed below.

- DIN EN 62471:2009-03 Testing of photobiological safety

The conformity assessment was carried out in accordance with Article 52 paragraph 7 of the EU MDR 2017/745. The products are marked with the CE mark according to EU-MDR 2017/745 Annex V. The complete technical documentation according to EU-MDR Annex II and III is kept at the above address and can be presented to the responsible national supervisory authority at any time.

Pforzheim 03.06.2024
(Place and date of issue)

Sven Cermak, Owner