## RICHARD CERMAK

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## EC declaration of conformity Valid until December 31, 2024

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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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:

NOVA
LUX
CE-LIGHT
LUNA
MAGIC
WONDER

Article no.:

NO100, NO110D, NO110DW, NO150D, NO160D, NO160DW
LX200D, LX210D, LX210DW, LX210D
CE250D, CE260D, CE260DW
LU 300D
MA350D, MA350DW
WO400D, WO410D, WO410DW
according to Annex VIII, Paragraph 6, 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.

(Place and date of issue)

Richard Cermak
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Amtsgericht Mannheim HRA 503550 USt.-Id: DE813013340

