### RICHARD CERMAK



Minitaschenlampen Inh. Sven Cermak e.K.

Tel. 07231/106 105 Fax. 07231/17790 E-Mail: info@richard-cermak.de

RICHARD CERMAK Minitaschenlampen, Maximilianstr. 16 a,75172 Pforzheim

## **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

### Richard Cermak Minitaschenlampen, Maximilianstr.16a, 75172 Pforzheim

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

NO100, NO110D, NO110DW, NO150D, NO160D, NO160DW

LUX

LX200D, LX210D, LX210DW, LX210D

**CE-LIGHT** 

CE250D, CE260D, CE260DW

LUNA

LU 300D

MAGIC

MA350D, MA350DW

WONDER

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.

Morcheim, 01.01.2021

(Place and date of issue)

Hichard Cermak
----Minitaschenlampen/Penlights
Maximilia⊕sten16æ/ri7€il√2 Pforzheim
Tel.: 07231-106105
www.penlights.de

Amtsgericht Mannheim HRA 503550 USt.-Id: DE813013340

Richard Cermak Minitaschenlampen Inh. Sven Cermak e.K. Maximilianstr. 16 a 75172 Pforzheim / Deutschland

Inhaber: Sven Cermak www.penlights.de info@richard-cermak.de