



EMA-LED GmbH · Ottostrasse 3 · 63785 Obernburg am Main



EU-Declaration of Conformity

According to Regulation (EU) 2017/745 of the European Parliament and of the Council, Article 19.

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| Manufacturers Name: | EMA-LED GmbH |
| Manufacturers Address: | Ottostraße 3, 63785 Obernburg am Main, Germany |
| SRN (Single Registration Number): | DE-MF-000017063 |
| Basic UDI-DI: | 426025797EMALEDLIGHTPY |
| Name of the Device: | EMALED |

Products:

| Model | Code | Intended purpose |
|---------------------|--------|--|
| EMALED 560/500 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/500 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/500 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/500 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300+ V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300+ V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300+ /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/300+ | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/560 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/560 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/560 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/560 | 12-282 | Operating light, double, ceiling mounted |

EMA-LED GmbH
 Ottostrasse 3
 63785 Obernburg am Main
 Telefon +49 (0) 6022 206 811
 Fax +49 (0) 6022 208 754

Bankverbindung
 Sparkasse Miltenberg-Obernburg
 IBAN DE66 7965 0000 0500 8315 08
 BIC BYLADEM1MIL

Handelsregister Aschaffenburg Nr. HRB 9680
 USt.-Id-Nr. DE250520822
 Geschäftsführerin Natalie Ster
 www.emaled.de
 info@emaled.de





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| EMALED 500/300 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300+ V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300+ V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300+ /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/300+ | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/500 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/500 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/500 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 500/500 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 300/300 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 300/300+ | 12-282 | Operating light, double, ceiling mounted |
| EMALED 300/300 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 300/300+/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 560/560/560 | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/500/500 | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/300 | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/300 V | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/300 V/M | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/560 V | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/560 V/M | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/560/500 | 12-282 | Operating light, triple, ceiling mounted |



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| EMALED 500/500/500 | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/500/300 | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560/500/300+ | 12-282 | Operating light, triple, ceiling mounted |
| EMALED 560 | 12-282 | Operating light, single, ceiling mounted |
| EMALED 560 V/M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 560 /M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 560 V | 12-282 | Operating light, single, ceiling mounted |
| EMALED 560 F | 12-282 | Operating light, mobile |
| EMALED 560 F V | 12-282 | Operating light, mobile |
| EMALED 560 M | 12-282 | Operating light, mobile with battery |
| EMALED 560 VM | 12-282 | Operating light, mobile with battery |
| EMALED 500 | 12-282 | Operating light, single, ceiling mounted |
| EMALED 500 /M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 500 V/M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 500 V | 12-282 | Operating light, single, ceiling mounted |
| EMALED 500 M | 12-282 | Operating light, mobile with battery |
| EMALED 500 V M | 12-282 | Operating light, mobile with battery |
| EMALED 500 F | 12-282 | Operating light, mobile |
| EMALED 500 F V | 12-282 | Operating light, mobile |
| EMALED 300 D | 12-282 | Operating light, single, ceiling mounted |
| EMALED 300D+ | 12-282 | Operating light, single, ceiling mounted |
| EMALED 300 / M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 300+ / M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 300 W | 12-282 | Operating light, wall mounted |



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| EMALED 300W+ | 12-282 | Operating light, wall mounted |
| EMALED 300 M | 12-282 | Operating light, mobile with battery |
| EMALED 300 M+ | 12-282 | Operating light, mobile with battery |
| EMALED 300 F | 12-282 | Operating light, mobile |
| EMALED 300 F+ | 12-282 | Operating light, mobile |
| EMALED 200 D | 15-866 | Examination light, ceiling mounted |
| EMALED 200 D+ | 15-866 | Examination light, ceiling mounted |
| EMALED 200 W | 12-276 | Examination light, wall mounted |
| EMALED 200 W+ | 12-276 | Examination light, wall mounted |
| EMALED 200 F | 12-276 | Examination light, mobile |
| EMALED 200 F+ | 12-276 | Examination light, mobile |
| EMALED 101 M-30 CT | 12-276 | Examination light, mobile |
| EMALED 101 M-30 | 12-276 | Examination light, mobile |
| EMALED 101 M-50 | 12-276 | Examination light, mobile |
| EMALED 101 AM-30 | 12-276 | Examination light, mobile with battery |
| EMALED 101 AM-30 CT | 12-276 | Examination light, mobile with battery |
| EMALED 101 AM-50 | 12-276 | Examination light, mobile with battery |
| EMALED 101 W-30 CT | 12-276 | Examination light, wall mounted |
| EMALED 101 M-30 | 12-276 | Examination light, mobile |
| EMALED 101 W-50 | 12-276 | Examination light, wall mounted |
| EMALED 101 AW-30 CT | 12-276 | Examination light, wall mounted with battery |
| EMALED 101 AW-30 | 12-276 | Examination light, wall mounted with battery |
| EMALED 101 AW-50 | 12-276 | Examination light, wall mounted with battery |
| EMALED 101 T-30 CT | 12-276 | Examination light, table mounted |



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| EMALED 101 T-30 | 12-276 | Examination light, table mounted |
| EMALED 101 T-50 | 12-276 | Examination light, table mounted |
| EMALED 101 AT-30 CT | 12-276 | Examination light, table mounted, with battery |
| EMALED 101 AT-30 | 12-276 | Examination light, table mounted, with battery |
| EMALED 101 AT-50 | 12-276 | Examination light, table mounted, with battery |
| EMALED 602 | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602/602 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602 V | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602/602 V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602/M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602/602/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602L V | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602L/M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 602L/602L | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/602L V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/602L/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/602L V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602/602L | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602/602L V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/402 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/402V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602L/402/M | 12-282 | Operating light, double, ceiling mounted |



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| EMALED 602L/402V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 602 F | 12-282 | Operating light, mobile |
| EMALED 602 FV | 12-282 | Operating light, mobile |
| EMALED 602 M | 12-282 | Operating light, mobile with battery |
| EMALED 602 MV | 12-282 | Operating light, mobile with battery |
| EMALED 602L F | 12-282 | Operating light, mobile |
| EMALED 602L FV | 12-282 | Operating light, mobile |
| EMALED 602L M | 12-282 | Operating light, mobile with battery |
| EMALED 602L MV | 12-282 | Operating light, mobile with battery |
| EMALED 402 F | 12-282 | Operating light, mobile |
| EMALED 402 M | 12-282 | Operating light, mobile with battery |
| EMALED 402 FV | 12-282 | Operating light, mobile |
| EMALED 402 MV | 12-282 | Operating light, mobile with battery |
| EMALED 402 V/M | 12-282 | Operating light, single, ceiling mounted |
| EMALED 402/402 | 12-282 | Operating light, double, ceiling mounted |
| EMALED 402/402V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 402/402 /M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 402/402 V/M | 12-282 | Operating light, double, ceiling mounted |
| EMALED 402 D | 12-282 | Operating light, single, ceiling mounted |
| EMALED 402 V | 12-282 | Operating light, single, ceiling mounted |
| EMALED 402 W | 12-282 | Operating light, wall mounted |
| EMALED 402 WV | 12-282 | Operating light, wall mounted |
| EMALED 402/202V | 12-282 | Operating light, double, ceiling mounted |
| EMALED 402/202 | 12-282 | Operating light, double, ceiling mounted |



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| EMALED 202 W | 12-282 | Examination light, wall mounted |
| EMALED 202 W + | 12-282 | Examination light, wall mounted |
| EMALED 202 D | 12-282 | Examination light, ceiling mounted |
| EMALED 202 D + | 12-282 | Examination light, ceiling mounted |
| EMALED 200F | 12-282 | Examination light, mobile |
| EMALED 202 F + | 12-282 | Examination light, mobile |
| EMALED 202 M | 12-282 | Examination light, mobile with battery |
| EMALED 200 M + | 12-282 | Examination light, mobile with battery |

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| Equipment | <p>Intermediate Frame ZG 560 ZG 300 ZG 200</p> <p>Ceiling Disk DS 560 DS 300 DS 200</p> <p>EMALED Controller EMACAM Controller</p> |
| Intended use: | <p>The EMALED systems are used, depending on the variant:</p> <ul style="list-style-type: none"> - for medical examination - for use in the operation room, intensive care and medical environment. |
| Classification (Regulation (EU), 2017/745, Annex III): | I |
| Conformity assessment route: | <p>EMA-LED GmbH uses the following conformity assessment route for these class I medical devices: Regulation (EU) 2017/745, Annex II and III with subsequent declaration of conformity according to Annex IV and CE marking according to Annex V.</p> |



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This declaration of conformity is issued under the sole responsibility of EMA-LED GmbH.

We hereby declare that the medical device specified above meet the provision of the Regulation MDR 2017/745 with the applicable harmonized standards.

Furthermore, we declare under our sole responsibility that the subject of the declaration described above complies with the provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The validity period of this declaration is limited by the issuing of a revised declaration as soon as the intended use is changed or the above-mentioned product is modified in such a way that the benefit-risk ratio is affected. This declaration confirms compliance with the mentioned guidelines. However, it does not include the assurance of certain attributes of the product. The safety instructions of the accompanying documents, delivered with the product have to be observed.

Place: Obernburg am Main

Date: 2023-12-07

Natalie Ster

General Manager of EMA-LED GmbH