



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.

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
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Bankverbindung
Sparkasse Miltenberg-Obernburg
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Handelsregister Aschaffenburg Nr. HRB 9680
USt.-Id-Nr. DE250520822
Geschäftsführerin Natalie Ster
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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 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

Equipment	<p>Intermediate Frame</p> <p>ZG 560</p> <p>ZG 300</p> <p>ZG 200</p> <p>Ceiling Disk</p> <p>DS 560</p> <p>DS 300</p> <p>DS 200</p> <p>EMALED Controller</p> <p>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