

EG - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY

Für das nachstehend bezeichnete Medizinprodukt
For the following named medical device

Produktname Name of product:	LUXAMED LED Praxisleuchte, siehe Liste im Anhang LUXAMED LED examination lamp, see attached list
Basis UDI / basic UDI	426038196LeuchtenJC
Hersteller / Manufacturer:	LUXAMED GmbH & Co. KG
Anschrift / Address:	Daniel-Weil-Straße 3 89143 Blaubeuren Germany

wird hiermit in alleiniger Verantwortung erklärt, dass es die Anforderungen der Verordnung (EU) 2017/745 (MDR) erfüllt und nach Anhang VIII, Regel 10, der Klasse I zugeordnet ist, nach Anhang I der Verordnung (EU) 2017/745 (MDR) alle anwendbaren grundlegenden Sicherheits- und Leistungsanforderungen erfüllen.
Gültig bis / Bis zur Änderung eines in der Tabelle genannten Produkte, längstens aber bis zum 22.04.2023.

we declare in sole responsibility, that the provisions of Regulation (EU) 2017/745 which apply to them are fulfilled and according to annex VIII, rule 10, assigned to class I, according to Annex I of Regulation (EU) 2017/745 (MDR) meet all applicable basic safety and performance requirements.
Validity / Until the change of one of the products specified in the table, but at the latest until 22.04.2023.

Folgende angewandt harmonisierte Normen, nationale Normen oder andere normative Dokumente werden erfüllt:

Following applied harmonised standards, national standards or other normative documents are fulfilled

(EU) 2017/745 (MDR)
EN ISO 13485
IEC 60601-1
IEC 60601-1-2
IEC 62471

Blaubeuren, 2021-02-16



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Produktliste

Bezeichnung	Variante	REF
LED Praxisleuchte	auf 5-Fuß-Stativ, pulverbeschichtet	U1.111.014
LED Praxisleuchte	auf 5-Fuß-Stativ, pulverbeschichtet, mit Griff	U1.111.114
LED Praxisleuchte	with 5-feet-stand, powder coated, black	U1.121.014
LED Praxisleuchte	with 5-feet-stand, with handle, black	U1.121.114
LED Praxisleuchte	with 5-feet-stand, powder coated, ice blue	U1.131.014
LED Praxisleuchte	with 5-feet-stand, with handle, ice blue	U1.131.114
LED Praxisleuchte	with 5-feet-stand, powder coated, rape yellow	U1.141.014
LED Praxisleuchte	with 5-feet-stand, with handle, rape yellow	U1.141.114
LED Praxisleuchte	with 5-feet-stand, powder coated, jade-green	U1.151.014
LED Praxisleuchte	with 5-feet-stand, with handle, jade-green	U1.151.114
LED Praxisleuchte	with 5-feet-stand, powder coated, delicate lilac	U1.161.014
LED Praxisleuchte	with 5-feet-stand, with handle, delicate lilac	U1.161.114
LED Praxisleuchte	FOCUS auf 5-Fuß-Stativ, pulverbeschichtet	U1.211.014
LED Praxisleuchte	FOCUS auf 5-Fuß-Stativ, pulverbeschichtet, mit Griff	U1.211.114
LED Praxisleuchte	Oberteil allein	U9.112.014
LED Praxisleuchte	Oberteil allein, mit Griff	U9.112.114
LED Praxisleuchte	Oberteil allein, Schwarz	U9.122.014
LED Praxisleuchte	Oberteil allein, mit Griff, Schwarz	U9.122.114
LED Praxisleuchte	Oberteil allein, Weissblau	U9.132.014
LED Praxisleuchte	Oberteil allein, mit Griff, Weissblau	U9.132.114
LED Praxisleuchte	Oberteil allein, Rapsgelb	U9.142.014
LED Praxisleuchte	Oberteil allein, mit Griff, Rapsgelb	U9.142.114
LED Praxisleuchte	Oberteil allein, Jade-Grün	U9.152.014
LED Praxisleuchte	Oberteil allein, mit Griff, Jade-Grün	U9.152.114
LED Praxisleuchte	Oberteil allein, Zartflieger	U9.162.014
LED Praxisleuchte	Oberteil allein, mit Griff, Zartflieger	U9.162.114

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Productlist

Product Name	Varity	REF
LED examination lamp	with 5-feet-stand, powder coated	U1.111.014
LED examination lamp	with 5-feet-stand, with handle	U1.111.114
LED examination lamp	with 5-feet-stand, powder coated, black	U1.121.014
LED examination lamp	with 5-feet-stand, with handle, black	U1.121.114
LED examination lamp	with 5-feet-stand, powder coated, ice blue	U1.131.014
LED examination lamp	with 5-feet-stand, with handle, ice blue	U1.131.114
LED examination lamp	with 5-feet-stand, powder coated, rape yellow	U1.141.014
LED examination lamp	with 5-feet-stand, with handle, rape yellow	U1.141.114
LED examination lamp	with 5-feet-stand, powder coated, jade-green	U1.151.014
LED examination lamp	with 5-feet-stand, with handle, jade-green	U1.151.114
LED examination lamp	with 5-feet-stand, powder coated, delicate lilac	U1.161.014
LED examination lamp	with 5-feet-stand, with handle, delicate lilac	U1.161.114
LED examination lamp	FOCUS with 5-feet-stand, powder coated	U1.211.014
LED examination lamp	FOCUS with 5-feet-stand, with handle	U1.211.114
LED examination lamp	upper-part, only	U9.112.014
LED examination lamp	upper-part, only, with handle	U9.112.114
LED examination lamp	upper-part, only, black	U9.122.014
LED examination lamp	upper-part, only, with handle, black	U9.122.114
LED examination lamp	upper-part, only, ice blue	U9.132.014
LED examination lamp	upper-part, only, with handle, ice blue	U9.132.114
LED examination lamp	upper-part, only, rape yellow	U9.142.014
LED examination lamp	upper-part, only, with handle, rape yellow	U9.142.114
LED examination lamp	upper-part, only, jade-green	U9.152.014
LED examination lamp	upper-part, only, with handle, jade-green	U9.152.114
LED examination lamp	upper-part, only, delicate lilac	U9.162.014
LED examination lamp	upper-part, only, with handle, delicate lilac	U9.162.114

Spare parts list

LED Examination Lamp	U9.112.014
LED Examination Lamp with handle	U9.112.114
5-feet-stand for LED Examination Lamp	U9.113.014
wall bracket for LED Examination Lamp	U5.232.014
table clamp for LED Examination Lamp	U5.242.014