

EU - KONFORMITÄTSERKLÄRUNG EU - DECLARATION OF CONFORMITY

Für das nachstehend bezeichnete Medizinprodukt
For the following named medical device

Produktname / Name of product: Dermatroskop LED, siehe Liste im Anhang / Dermatoscope LED, see attached list



Basis UDI-DI / Basic UDI-DI 426038196DermatroskopF9

Hersteller / Manufacturer: **LUXAMED** GmbH & Co. KG

SRN: DE-MF-000006437

Anschrift / Address: Daniel-Weil-Straße 3
89143 Blaubeuren
Germany

Zweckbestimmung / Intended use: Das LUXAMED® Dermatroskop LED ist zur Untersuchung der Epidermis bei Mensch und Tier sowie als Beleuchtung bei nicht-invasiven Untersuchungen bestimmt. / The LUXAMED® dermatoscope LED is intended for examining the epidermis of humans and animals as well as lighting for non-invasive examinations.

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.
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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 produktspezifischen Normen werden in ihrer jeweils gültigen Fassung zur Darlegung der Konformität erfüllt
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Following product related standards are fulfilled in their currently valid version to demonstrate conformity

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- DIN EN ISO 10993-1
- IEC 62471

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Blaubeuren, 2022-12-06



Matthias Dubb
QMB

Produktliste

Bezeichnung	Variante	REF
LuxaScope Dermatoskop LED	2.5V LED Dermatoskop, schwarz	C1.416.114
LuxaScope Dermatoskop LED	2.5V LED Dermatoskop, weiß	C1.416.914
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / weißblau, Kontaktscheibe OHNE Skala	C1.416.934
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / rapsgelb, Kontaktscheibe OHNE Skala	C1.416.944
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / jadegrün, Kontaktscheibe OHNE Skala	C1.416.954
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / zartflieder, Kontaktscheibe OHNE Skala	C1.416.964
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / magenta, Kontaktscheibe OHNE Skala	C1.416.974
LuxaScope Dermatoskop LED	3.7V LED Dermatoskop, schwarz	C1.426.114
LuxaScope Dermatoskop LED	3.7V LED Dermatoskop, weiß	C1.426.914
LuxaScope Dermatoskop LED	2.5V LED Dermatoskop, schwarz, mit Skala	C1.516.114
LuxaScope Dermatoskop LED	2.5V LED Dermatoskop, weiß, mit Skala	C1.516.914
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / weißblau, Kontaktscheibe MIT Skala	C1.516.934
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / rapsgelb, Kontaktscheibe MIT Skala	C1.516.944
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / jadegrün, Kontaktscheibe MIT Skala	C1.516.954
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / zartflieder, Kontaktscheibe MIT Skala	C1.516.964
LuxaScope Dermatoskop LED	2.5 V LED "COLOUR-EDITION", weiß / magenta, Kontaktscheibe MIT Skala	C1.516.974
LuxaScope Dermatoskop LED	3.7V LED Dermatoskop, schwarz, mit Skala	C1.526.114
LuxaScope Dermatoskop LED	3.7V LED Dermatoskop, weiß, mit Skala	C1.526.914
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoskop, schwarz	C1.616.114
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoskop, weiß	C1.616.914
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoskop, schwarz, mit Skala	C1.716.114
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoskop, weiß, mit Skala	C1.716.914
LuxaScope Dermatoskop LED	2.5 V LED Dermatoskop, weiß, Kontaktscheibe OHNE Skala, KIDS	C1.816.914
LuxaScope Dermatoskop LED	2.5 V LED Dermatoskop, weiß, Kontaktscheibe MIT Skala, KIDS	C1.916.914

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Productlist

Product Name	Varity	REF
LuxaScope Dermatoscope LED	2.5V LED Dermatoscope, black	C1.416.114
LuxaScope Dermatoscope LED	2.5V LED Dermatoscope, white	C1.416.914
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / ice-blue, contact plate WITHOUT scale	C1.416.934
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / colza-yellow, contact plate WITHOUT scale	C1.416.944
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / jade-green, contact plate WITHOUT scale	C1.416.954
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / delicate-lilac, contact plate WITHOUT scale	C1.416.964
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / megenta, contact plate WITHOUT scale	C1.416.974
LuxaScope Dermatoscope LED	3.7V LED Dermatoscope, black	C1.426.114
LuxaScope Dermatoscope LED	3.7V LED Dermatoscope, white	C1.426.914
LuxaScope Dermatoscope LED	2.5V LED Dermatoscope, black, with scale	C1.516.114
LuxaScope Dermatoscope LED	2.5V LED Dermatoscope, white, with scale	C1.516.914
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / ice-blue, contact plate WITH scale	C1.516.934
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / colza-yellow, contact plate WITH scale	C1.516.944
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / jade-green, contact plate WITH scale	C1.516.954
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / delicate-lilac, contact plate WITH scale	C1.516.964
LuxaScope Dermatoscope LED	2.5 V LED "COLOUR-EDITION", white / megenta, contact plate WITH scale	C1.516.974
LuxaScope Dermatoscope LED	3.7V LED Dermatoscope, black, with scale	C1.526.114
LuxaScope Dermatoscope LED	3.7V LED Dermatoscope, white, with scale	C1.526.914
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoscope, black	C1.616.114
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoscope, white	C1.616.914
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoscope, black, with scale	C1.716.114
LuxaScope Dermatoskop CCT LED	2.5V LED Dermatoscope, white, with scale	C1.716.914
LuxaScope Dermatoscope LED	2.5 V LED Dermatoscope, white, contact plate WITHOUT scale, KIDS	C1.816.914
LuxaScope Dermatoscope LED	2.5 V LED Dermatoscope, white, contact plate WITH scale, KIDS	C1.916.914