

EG - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY

Für das nachstehend bezeichnete Medizinprodukt
For the following named medical device

Produktname
Name of product: LuxaScope Auris LED, siehe Liste im Anhang
LuxaScope Auris LED, see attached list

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 Richtlinie 93/42 EWG nach Anhang VII vom 14. Juni 1993 über Medizinprodukte unter Berücksichtigung der Änderungsrichtlinie 2007/47/EWG erfüllt und der Klasse I zugeordnet ist.
Diese EG-KONFORMITÄTSERKLÄRUNG behält Gültigkeit bis 26. April 2022.

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we declare in sole responsibility, that the provisions of the directive 93/42 EEC according to annex VII of 14th June 1993 concerning medical devices in consideration of change directive 2007/47/EEC which apply to them are fulfilled and assigned to class I.
This EC – DECLARATION OF CONFORMITY is valid until 26th April 2022.

Blaubeuren, 2019-12-02



Matthias Dubb
QMB

Dokumentbezeichnung	REV	Erstelldatum / Kurzzeichen	Freigabedatum / Kurzzeichen	Seite/Seite(n)
TD_03 Konformitätserklärung	07	2013-09-02Dub	2013-09-02 QMB	1 / 3

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Produktliste

Bezeichnung	Variante	REF
LuxaScope® Auris LED	2.5V LED Otoskop, schwarz	A1.416.114
LuxaScope® Auris LED	2.5V LED Otoskop, blau	A1.416.214
LuxaScope® Auris LED	2.5V LED Otoskop, grau	A1.416.314
LuxaScope® Auris LED	2.5V LED Otoskop, weiß	A1.416.914
LuxaScope® Auris LED	2.5 V LED Otoskop KIDS	A1.516.914
LuxaScope® Auris LED	2.5V LED Otoskop, weissblau	A1.416.934
LuxaScope® Auris LED	2.5V LED Otoskop, rapsgelb	A1.416.944
LuxaScope® Auris LED	2.5V LED Otoskop, jadegrün	A1.416.954
LuxaScope® Auris LED	2.5V LED Otoskop, zartflieder	A1.416.964
LuxaScope® Auris LED	2.5V LED Otoskop, magenta	A1.416.974
LuxaScope® Auris CCT LED	2.5V LED Otoskop, schwarz	A1.616.114
LuxaScope® Auris CCT LED	2.5V LED Otoskop, blau	A1.616.214
LuxaScope® Auris CCT LED	2.5V LED Otoskop, grau	A1.616.314
LuxaScope® Auris CCT LED	2.5V LED Otoskop, weiß	A1.616.914
LuxaScope® Auris LED	3.7V LED Otoskop, schwarz	A1.426.114
LuxaScope® Auris LED	3.7V LED Otoskop, blau	A1.426.214
LuxaScope® Auris LED	3.7V LED Otoskop, grau	A1.426.314
LuxaScope® Auris LED	3.7V LED Otoskop, weiß	A1.426.914
Zubehör 2.5 mm Ohrtrichter, grau, 100 Stück, lose		A5.101.144
Zubehör 4.0 mm Ohrtrichter, grau, 100 Stück, lose		A5.102.144
Zubehör 2.5 mm Ohrtrichter, grau, 1000 Stück je 100 Stück, lose		A5.101.164
Zubehör 4.0 mm Ohrtrichter, grau, 1000 Stück je 100 Stück, lose		A5.102.164
Zubehör 2.5 mm Ohrtrichter, grau, 1000 Stück, lose		A5.101.184
Zubehör 4.0 mm Ohrtrichter, grau, 1000 Stück, lose		A5.102.184
Zubehör Ball inkl. Schlauch und Adapter für pneumatischen Test		A5.201.112

Productlist

Product Name	Varity	REF
LuxaScope® Auris LED	2.5V LED Ootoscope, black	A1.416.114
LuxaScope® Auris LED	2.5V LED Ootoscope, blue	A1.416.214
LuxaScope® Auris LED	2.5V LED Ootoscope, grey	A1.416.314
LuxaScope® Auris LED	2.5V LED Ootoscope, white	A1.416.914
LuxaScope® Auris LED	2.5 V LED Ootoscope KIDS	A1.516.914
LuxaScope® Auris LED	2.5V LED Ootoscope, ice-blue	A1.416.934
LuxaScope® Auris LED	2.5V LED Ootoscope, colsar yellow	A1.416.944

Dokumentbezeichnung	REV	Erstelldatum / Kurzzeichen	Freigabedatum / Kurzzeichen	Seite/Seite(n)
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LuxaScope® Auris LED	2.5V LED Otoscope, jade-green	A1.416.954
LuxaScope® Auris LED	2.5V LED Otoscope, delicate lilac	A1.416.964
LuxaScope® Auris LED	2.5V LED Otoscope, magenta	A1.416.974
LuxaScope® Auris CCT LED	2.5V LED Otoscope, black	A1.616.114
LuxaScope® Auris CCT LED	2.5V LED Otoscope, blue	A1.616.214
LuxaScope® Auris CCT LED	2.5V LED Otoscope, grey	A1.616.314
LuxaScope® Auris CCT LED	2.5V LED Otoscope, white	A1.616.914
LuxaScope® Auris LED	3.7V LED Otoscope, black	A1.426.114
LuxaScope® Auris LED	3.7V LED Otoscope, blue	A1.426.214
LuxaScope® Auris LED	3.7V LED Otoscope, grey	A1.426.314
LuxaScope® Auris LED	3.7V LED Otoscope, white	A1.426.914
2.5 mm ear tips, grey, 100 pieces, in bulk		A5.101.144
4.0 mm ear tips, grey, 100 pieces, in bulk		A5.102.144
2.5 mm ear tips, grey, 1000 pieces per 100 pieces, in bulk		A5.101.164
4.0 mm ear tips, grey, 1000 pieces per 100 pieces, in bulk		A5.102.164
2.5 mm ear tips, grey, 1000 pieces, in bulk		A5.101.184
4.0 mm ear tips, grey, 1000 pieces, in bulk		A5.102.184
Ball incl. tube and adapter for pneumatic test		A5.201.112