

EU - KONFORMITÄTSERKLÄRUNG EU - 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



Basis UDI-DI / Basic UDI-DI: 426038196OtoskopYN

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

SRN: DE-MF-000006437

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

Zweckbestimmung / Intended use: LUXAMED® LuxaScope Auris LED Otoskope sind zur
Untersuchung des äußeren Gehörgangs bestimmt. /
LUXAMED® LuxaScope Auris LED otoscopes are to be used
for the examination of the outer ear canal

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

Blaubeuren, 2021-12-19



Matthias Dubb
QMB

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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, 250 Stück, lose		A5.101.124
Zubehör 4.0 mm Ohrtrichter, grau, 250 Stück, lose		A5.102.124
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

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Productlist

Product Name	Variety	REF
LuxaScope® Auris LED	2.5V LED Otoscope, black	A1.416.114
LuxaScope® Auris LED	2.5V LED Otoscope, blue	A1.416.214
LuxaScope® Auris LED	2.5V LED Otoscope, grey	A1.416.314
LuxaScope® Auris LED	2.5V LED Otoscope, white	A1.416.914
LuxaScope® Auris LED	2.5 V LED Otoscope KIDS	A1.516.914
LuxaScope® Auris LED	2.5V LED Otoscope, ice-blue	A1.416.934
LuxaScope® Auris LED	2.5V LED Otoscope, colsar yellow	A1.416.944
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, 250 pieces, in bulk		A5.101.124
4.0 mm ear tips, grey, 250 pieces, in bulk		A5.102.124
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