

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 zur Änderung eines in der Tabelle genannten Produkte.

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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.
Valid until the change of one of the products specified in the table.

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
- IEC 60601-1-9
- DIN EN ISO 10993-1
- IEC 62471

Blaubeuren, 2023-04-06



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 2.5 mm Ohrtrichter, grau, 300 Stück je 30 Stück, lose | | A5.101.194 |
| Zubehör 4.0 mm Ohrtrichter, grau, 300 Stück je 30 Stück, lose | | A5.102.194 |
| Zubehör Ball inkl. Schlauch und Adapter für pneumatischen Test | | A5.201.112 |
| Zubehör Spender für Ohrtrichter | | A5.401.112 |

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Productlist

| Product Name | Varity | 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 |
| 2.5 mm ear tips, grey, 300 pieces (10x30 pcs. plug-packed) | | A5.101.194 |
| 4.0 mm ear tips, grey, 300 pieces (10x30 pcs. plug-packed) | | A5.102.194 |
| Ball incl. tube and adapter for pneumatic test | | A5.201.112 |
| Ear funnel dispenser | | A5.401.112 |