

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
Basis UDI / basic UDI	426038196OtoskopYN
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.

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

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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, 2020-04-23

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, rapsgeib	A1.416.944
LuxaScope® Auris LED	2.5V LED Otoskop, jadegeün	A1.416.954
LuxaScope® Auris LED	2.5V LED Otoskop, zartflieber	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 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

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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, 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