

# EU-KONFORMITÄTSERKLÄRUNG

## EU-DECLARATION OF CONFORMITY



Hersteller / Manufacturer: Kirchner & Wilhelm GmbH + Co KG  
Eberhardstr. 56  
71679 Asperg  
Deutschland / Germany

Produktfamilie /  
Product family: **Otoskope**  
Otosopes

Zweckbestimmung /  
Intended use: Diagnostikinstrument für die medizinischen Untersuchung des äußeren Gehörgangs bis zum Trommelfell. Für Sets gilt zusätzlich die Konformitätserklärung "Ophthalmoskop, direkt".  
Diagnostic instrument for medical examination of the external auditory canal up to the eardrum. For sets, the declaration of conformity "Ophthalmoscopes, direct" also applies.

Hiermit erklären wir in alleiniger Verantwortung, dass:

- die oben genannte Produktfamilie den einschlägigen Bestimmungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht.  
Die Medizinprodukte werden nach Verordnung (EU) 2017/745 Anhang VIII der Klasse I zugeordnet.
- die oben genannte Produktfamilie mit allen Komponenten den einschlägigen Bestimmungen der Richtlinie 2011/65/EU (RoHS) und der Richtlinie 2014/30/EU (EMV) sowie den zutreffenden Umsetzungen in nationale Gesetze entspricht.

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We hereby declare in sole responsibility that:

- the product family named above complies with the relevant provisions of Regulation (EU) 2017/745 concerning medical devices.  
The medical devices are assigned to Class I according to Regulation (EU) 2017/745 Annex VIII.
- the product family named above with all components complies with the relevant provisions of Directive 2011/65/EU (RoHS) and Directive 2014/30/EU (EMC) as well as the applicable implementations in national laws.

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**Basis UDI-DI / Basic UDI-DI:** 4030155KaWe0101YR

Diese Konformitätserklärung ist bis zur Ausstellung einer neuen Version gültig.  
This declaration of conformity is valid until a new version is issued.

Asperg, 2021-05-06

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R. Kirchner-Gottschalk  
Geschäftsleitung / President

## Liste der zur Konformitätserklärung zugehörigen Produkte

### Otoskope

## List of devices accompanying the declaration of conformity

### Otosopes

<u>Artikel-Nr. / Ref</u>	<u>Bezeichnung</u>	<u>Denomination</u>
01.11110.001	EUROLIGHT C10 Otoskop mit Schraubverschluss	EUROLIGHT C10 otoscope with screw closure system
01.11130.001	EUROLIGHT C30 Otoskop mit Clic-Verschluss	EUROLIGHT C30 otoscope with clic-closure system
01.11330.001	EUROLIGHT F.O.30 Otoskop mit autom. Clic-Verschluss 2,5 V	EUROLIGHT F.O.30 otoscope with autom. clic-system, 2,5 V
01.11430.101	EUROLIGHT F.O.30 Otoskop inkl.Ladebatt. Lilon (C)	EUROLIGHT F.O.30 otoscope incl. charg. battery Lilon(C)
01.11430.811	EUROLIGHT F.O.30 Otoskop mit Ladestecker 240V+Akku 3,5V	EUROLIGHT F.O.30 otoscope with charg.plug 240V+accu 3.5V
01.11530.002	EUROLIGHT F.O.30 LED standard Otoskop, 2,5 V	EUROLIGHT F.O.30 LED standard otoscope,2.5 V
01.11534.001	EUROLIGHT C30 OP LED standard Otoskop, 2,5 V	EUROLIGHT C30 OP LED standard otoscope,2.5 V
01.11830.101	EUROLIGHT F.O.30 LED high power Otoskop, 3,5 V	EUROLIGHT F.O.30 LED high power otoscope, 3.5V
01.12110.001	COMBILIGHT C10 Otoskop mit Kunststoffkopf, 2,5 V	COMBILIGHT C10 otoscope with plastic head, 2,5 V
01.12330.001	COMBILIGHT F.O. 30 Otoskop, 2,5 V	COMBILIGHT F.O.30 otoscope,2,5 V
01.12430.101	COMBILIGHT F.O.30 Otoskop inkl. Ladebatterie Lilon (C)	COMBILIGHT F.O.30 otoscope incl. charg. battery Lilon (C)
01.12430.811	COMBILIGHT F.O.30 Otoskop mit Ladestecker 240V+Akku 3,5V	COMBILIGHT F.O.30 otoscope with charg.plug 240V+accu 3.5V
01.12530.002	COMBILIGHT F.O.30 LED standard Otoskop, 2,5 V	COMBILIGHT F.O.30LED standard otoscope, 2.5 V
01.12830.101	COMBILIGHT F.O.30 LED high power Otoskop, 3,5 V	COMBILIGHT F.O.30 LED high power otoscope, 3.5V
01.13100.021	PICCOLIGHT C Otoskop, night mit Ohrtrichtern, Stofftasche	PICCOLIGHT C otoscope, night with ear funnels, cloth bag
01.13100.232	PICCOLIGHT C Otoskop, sky mit Ohrtrichtern, Stofftasche	PICCOLIGHT C otoscope, sky with ear funnels, cloth bag

01.13100.262	PICCOLIGHT C Otokop, stone mit Ohrtrichtern, Stofftasche	PICCOLIGHT C otoscope, stone with ear funnels, cloth bag
01.13300.021	PICCOLIGHT F.O. Otokop night mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O. otoscope night, ear funnels, cloth bag
01.13300.232	PICCOLIGHT F.O. Otokop, sky mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O. otoscope, sky with ear funnels, cloth bag
01.13300.262	PICCOLIGHT F.O. Otokop, stone mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O. otoscope, stone with ear funnels, cloth bag
01.13500.021	PICCOLIGHT F.O. LED standard, Otokop, night,	PICCOLIGHT F.O. LED standard, otoscope, night,
01.13500.232	PICCOLIGHT F.O. LED standard, Otokop, sky,	PICCOLIGHT F.O. LED standard, otoscope, sky,
01.13500.262	PICCOLIGHT F.O. LED standard, Otokop, stone,	PICCOLIGHT F.O. LED standard, otoscope, stone,
01.13600.022	PICCOLIGHT F.O. LED high power, Otokop, night,	PICCOLIGHT F.O. LED high power, otoscope, night,
01.13600.232	PICCOLIGHT F.O. LED high power, Otokop, sky,	PICCOLIGHT F.O. LED high power, otoscope, sky,
01.13600.262	PICCOLIGHT F.O. LED high power, Otokop, stone,	PICCOLIGHT F.O. LED high power, otoscope, stone,
01.73320.021	Otokop-Kopf, XL, allein, night, zu PICCOLIGHT C, 3,5V	Otoscope head, XL, only, night, for PICCOLIGHT C, 3.5V
01.73550.021	Otokop-Kopf, allein, night zu PICCOLIGHT F.O. LED high	Otoscope head, only, night to PICCOLIGHT F.O. LED high
01.78501.001	Balladapter aus Metall für PICCOLIGHT und COMBILIGHT	Metal ball adapter for PICCOLIGHT and COMBILIGHT
01.78502.001	Ball für pneumatischen Test	Otoscope ball for pneumatic
02.01000.002	BASIC-SET COMBILIGHT C10 Otokop	BASIC-SET COMBILIGHT C10 otoscope
02.01008.002	BASIC-SET COMBILIGHT C10/E15 Ophthalmoskop und Otokop	BASIC-SET COMBILIGHT C10/E15 ophthalmoscope and otoscope
02.01104.002	BASIC-SET COMBILIGHT C10/E16 Ophthalmoskop und Otokop	BASIC-SET COMBILIGHT C10/E16 ophthalmoscope and otoscope
02.11001.002	BASIC-SET COMBILIGHT C10/E10 Ophthalmoskop und Otokop	BASIC-SET COMBILIGHT C10/E10 ophthalmoscope and otoscope
02.11002.001	EUROLIGHT C10/E10 SET Ophthalmoskop und Otokop	EUROLIGHT C10/E10 SET ophthalmoscope and otoscope

02.15008.003	KaWe EUROLIGHT PRO-SET LED Ophthalmoskop und Otoskop	KaWe EUROLIGHT PRO-SET LED ophthalmoscope and otoscope
02.18004.002	EUROLIGHT F.O.30 LED/E36 SET Ophthalmoskop und Otoskop,3,5V	EUROLIGHT F.O.30 LED/E36 SET ophthalmoscope+otoscope, 3.5 V
02.23004.001	COMBILIGHT F.O.30/E36 (EU) SET Ophthalmoskop und Otoskop,2,5V	COMBILIGHT F.O.30/E36 (EU) SET ophthalmoscope+otoscope, 2.5 V
02.23014.002	COMBILIGHT F.O.30/E36 (EU)SET+ Ophthalmoskop und Otoskop,2,5V	COMBILIGHT F.O.30/E36 (EU)SET+ ophthalmoscope+otoscope, 2.5 V
02.24004.102	COMBILIGHT F.O.30/E36 (EU) SET Ophthalmoskop und Otoskop,3,5V	COMBILIGHT F.O.30/E36 (EU) SET ophthalmoscope+otoscope, 3.5 V
02.24005.102	COMBILIGHT F.O.30/E36 (US) SET Ophthalmoskop und Otoskop,3,5V	COMBILIGHT F.O.30/E36 (US) SET ophthalmoscope+otoscope, 3.5 V
02.25004.002	COMBILIGHT F.O.30 LED/E36 SET Ophthalmoskop und Otoskop,2,5V	COMBILIGHT F.O.30 LED/E36 SET ophthalmoscope+otoscope, 2.5 V
02.28014.002	COMBILIGHT F.O.30 LED/E36 SET Ophthalmoskop und Otoskop,3,5V	COMBILIGHT F.O.30 LED/E36 SET ophthalmoscope+otoscope, 3.5 V
02.31001.021	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop C, night	PICCOLIGHT SET ophthalmoscope E50 and otoscope C,night
02.31001.232	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop C, sky	PICCOLIGHT SET ophthalmoscope E50 and otoscope C,sky
02.31001.262	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop C, stone	PICCOLIGHT SET ophthalmoscope E50 and otoscope C,stone
02.33001.021	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop F.O., night	PICCOLIGHT SET ophthalmoscope E50 and otoscope F.O., night
02.33001.232	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop F.O., sky	PICCOLIGHT SET ophthalmoscope E50 and otoscope F.O., sky
02.33001.262	PICCOLIGHT SET Ophthalmoskop E50 und Otoskop F.O., stone	PICCOLIGHT SET ophthalmoscope E50 and otoscope F.O., stone
02.33404.022	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O.,night, EU	PICCOLIGHT SET ophthalmoscope E56 and otosc. F.O., night, EU
02.33404.232	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O., sky, EU	PICCOLIGHT SET ophthalmoscope E56 and otoscope F.O., sky, EU
02.33404.262	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O., stone,EU	PICCOLIGHT SET ophthalmoscope E56 and otoscope F.O., stone, EU
02.33405.022	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O., night, US	PICCOLIGHT SET ophthalmoscope E56 and otoscope F.O., night, US
02.33405.232	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O., sky, US	PICCOLIGHT SET ophthalmoscope E56 and otoscope F.O., sky, US

02.33405.262	PICCOLIGHT SET Ophthalmoskop E56 und Otoskop F.O., stone, US	PICCOLIGHT SET ophthalmoscope E56 and otoscope F.O., stone, US
02.35404.232	PICCOLIGHT SET Ophth. E56/Otoskop F.O.LED standard, sky, EU	PICCOLIGHT SET ophth. E56/otoscope F.O.LED standard, sky, EU
02.35404.262	PICCOLIGHT SET Ophth. E56/Otoskop F.O.LED standard, stone, EU	PICCOLIGHT SET ophth. E56/otoscope F.O.LED standard, stone, EU
02.35405.022	PICCOLIGHT SET Ophth. E56/Otoskop F.O.LED standard, night, US	PICCOLIGHT SET ophth. E56/otoscope F.O.LED standard, night, US
02.35405.232	PICCOLIGHT SET Ophth. E56/Otoskop F.O.LED standard, sky, US	PICCOLIGHT SET ophth. E56/otoscope F.O.LED standard, sky, US
02.35405.262	PICCOLIGHT SET Ophth. E56/Otoskop F.O.LED standard, stone, US	PICCOLIGHT SET ophth. E56/otoscope F.O.LED standard, stone, US
02.37405.021	PICCOLIGHT SET F.O./E56 LED, night	PICCOLIGHT SET F.O./E56 LED, night
02.37405.231	PICCOLIGHT SET F.O./E56 LED, sky	PICCOLIGHT SET F.O./E56 LED, sky
02.37405.261	PICCOLIGHT SET F.O./E56 LED, stone	PICCOLIGHT SET F.O./E56 LED, stone
12.80110.712	Ladebatterie, klein Nickel-Metallhydrid, 2,5 V(AA)	Rechargeable battery small nickel-metal hydrid, 2.5 V(AA)
12.80110.722	Ladebatterie, mittel Nickel-Metallhydrid	Rechargeable battery medium nickel metal hydride
12.80120.712	Ladebatterie, klein Nickel-Metallhydrid, 3,5 V	Rechargeable battery small nickel metal hydride, 3.5 V
12.80120.742	Akku kurz 3,5 V, allein	Accu short 3.5 V, alone
12.80220.722	Ladebatterie, mittel, Lithium-Ion, 3,5 V (C), (Lilon)	Rechargeable battery, medium Lithium-Ion, 3.5 V (C),(Lilon)