

# EU-KONFORMITÄTSERKLÄRUNG

## EU-DECLARATION OF CONFORMITY



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

Produktfamilie /  
Product family: **Otoskope**  
Otoscopes

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.

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.

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

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

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

|              |                                                                    |                                                                     |
|--------------|--------------------------------------------------------------------|---------------------------------------------------------------------|
| 02.33405.262 | PICCOLIGHT SET Ophthalmoskop<br>E56 und Otoskop F.O., stone, US    | PICCOLIGHT SET ophthalmoscope<br>E56 and otoscope F.O., stone, US   |
| 02.35404.232 | PICCOLIGHT SET Ophth. E56/Otos-<br>kop F.O.LED standard, sky, EU   | PICCOLIGHT SET ophth. E56/oto-<br>scope F.O.LED standard, sky, EU   |
| 02.35404.262 | PICCOLIGHT SET Ophth. E56/Otos-<br>kop F.O.LED standard, stone, EU | PICCOLIGHT SET ophth. E56/oto-<br>scope F.O.LED standard, stone, EU |
| 02.35405.022 | PICCOLIGHT SET Ophth. E56/Otos-<br>kop F.O.LED standard, night, US | PICCOLIGHT SET ophth. E56/oto-<br>scope F.O.LED standard, night, US |
| 02.35405.232 | PICCOLIGHT SET Ophth. E56/Otos-<br>kop F.O.LED standard, sky, US   | PICCOLIGHT SET ophth. E56/oto-<br>scope F.O.LED standard, sky, US   |
| 02.35405.262 | PICCOLIGHT SET Ophth. E56/Otos-<br>kop F.O.LED standard, stone, US | PICCOLIGHT SET ophth. E56/oto-<br>scope F.O.LED standard, stone, US |
| 02.37405.021 | PICCOLIGHT SET F.O./E56<br>LED, night                              | PICCOLIGHT SET F.O./E56<br>LED, night                               |
| 02.37405.231 | PICCOLIGHT SET F.O./E56<br>LED, sky                                | PICCOLIGHT SET F.O./E56<br>LED, sky                                 |
| 02.37405.261 | PICCOLIGHT SET F.O./E56<br>LED, stone                              | PICCOLIGHT SET F.O./E56<br>LED, stone                               |
| 12.80110.712 | Ladebatterie, klein Nickel-<br>Metallhydrid, 2,5 V(AA)             | Rechargeable battery small<br>nickel-metal hydrid, 2.5 V(AA)        |
| 12.80110.722 | Ladebatterie, mittel Nickel-<br>Metallhydrid                       | Rechargeable battery medium<br>nickel metal hydride                 |
| 12.80120.712 | Ladebatterie, klein Nickel-<br>Metallhydrid, 3,5 V                 | Rechargeable battery small<br>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-<br>Ion, 3,5 V (C), (Lilon)          | Rechargeable battery, medium<br>Lithium-Ion, 3.5 V (C),(Lilon)      |

# KaWe ПИККОЛАЙТ | KaWe PICCOLIGHT®

СЕРИЯ



Хорошо зарекомендовавшие себя отоскопы LED KaWe ПИККОЛАЙТ F.O. обеспечивают, благодаря высококачественной светотехнологии, оптимальными условиями для проведения простой терапии в области отоларингологии. LED-лампы отличаются превосходной светоотдачей и очень высоким показателем трансмиссии света, также впечатляют их длительный срок службы и прочность. Уже имеющиеся отоскопы с ксеноновым освещением KaWe ПИККОЛАЙТ F.O. легко переделать на отоскопы с LED – освещением, путем простой замены лампы. (» 190-191)

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## KaWe ПИККОЛАЙТ F.O. LED

- F.O. LED освещение
- интенсивность света  
прибл. 4.200 Люкс  
(на расстоянии 15 мм)
- срок службы лампы  
прибл. 50.000 ч.
- противоударный
- энергосберегающий
- батарейная рукоятка AA
- одноразовые  
ушные воронки (» 22)  
10 x Ø 2,5 мм  
10 x Ø 4,0 мм
- в сумке из ткани
- батарейки:  
2 Mignon (тип AA)



## KaWe ПИККОЛАЙТ F.O. LED

- F.O. LED освещение высокой мощности
- интенсивность света  
прибл. 18.400 Люкс  
(на расстоянии 15 мм)
- срок службы лампы  
прибл. 50.000 ч.
- противоударный
- энергосберегающий
- батарейная рукоятка AA
- одноразовые  
ушные воронки (» 22)  
10 x Ø 2,5 мм  
10 x Ø 4,0 мм
- в сумке из ткани
- батарейки:  
2 Mignon (тип AA)



|   |                                |  |                  |
|---|--------------------------------|--|------------------|
| 3 | F.O. LED   2,5 В   LED   найт  |  | REF 01.13500.021 |
|   | F.O. LED   2,5 В   LED   скай  |  | REF 01.13500.232 |
|   | F.O. LED   2,5 В   LED   стоун |  | REF 01.13500.262 |
|   | источник света                 |  | REF 12.75153.003 |

|   |                                  |  |                  |
|---|----------------------------------|--|------------------|
| 4 | F.O. LEDhp   2,5 В   LED   найт  |  | REF 01.13600.022 |
|   | F.O. LEDhp   2,5 В   LED   скай  |  | REF 01.13600.232 |
|   | F.O. LEDhp   2,5 В   LED   стоун |  | REF 01.13600.262 |
|   | источник света                   |  | REF 12.75152.003 |

Батарейки не входят в объем поставки!

LED LED лампа  
LEDhp LED лампа высокой мощности

REF Артикульный номер

