

Nr. KE-703

**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**
Nach Artikel 19 MDR
According to Article 19 MDR



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Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt
We declare under our sole responsibility that the medical device

Accessories for ENT and ophthalmological instruments

Artikel-Nr. von: / Article No. from:

Artikel-Nr. bis: / Article No. to:

allen Anforderungen der Verordnung (EU) 2017/745 entspricht. Das Verfahren gemäß den Vorgaben in Anhang II und Anhang III derselben Verordnung wurde eingehalten.

meets all the provisions of the regulation (EU) 2017/745. The procedure according to Annex II and Annex III of the above mentioned regulation has been followed.

Zweckbestimmung: Zubehör für HNO- und ophthalmologische Instrumente

Intended purpose: Accessories for ENT and ophthalmological instruments

Verordnungs-Klassifizierung nach Anhang VIII:
Regulation classification according to annex VIII:

**Klasse I
Class I**

Basic-UDI-DI:

4045396105628Z

Gemeinsame Spezifikationen:
Common specifications:

Keine gemeinsamen Spezifikationen
No common specifications

SRN- Nr.:

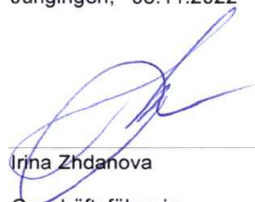
DE-MF-000006419

Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachter Produkte.
This declaration is effective for products placed on the market as of the date of issue.

Die festgestellte Konformität bezieht sich auch auf einzelne Komponenten und Bestandteile des Medizinprodukts, soweit diese vom Hersteller als Ersatzteile gesondert in den Verkehr gebracht werden.

The established conformity also relates to individual components and parts of the medical device as far as these are marketed separately by the manufacturer as spare parts or replacement parts.

Jungingen, 08.11.2022


Irina Zhdanova
Geschäftsführerin
Managing Director


Artur Pfister

Für die Einhaltung der Regulierungsvorschriften verantwortliche Person
Person responsible for regulatory compliance (PRRC)

We declare under our sole responsibility that the accessories for

ENT and ophthalmological instruments

meets all the provisions of the regulation (EU) 2017/745 on medical devices..

Regulation classification according Annex VIII: **Accessories Class I**

Replacement lamps vacuum

uni®, econom®

10421 Pack of 6 pcs. 2.7 V vacuum bulbs, otoscope uni®/speculight

10424 Pack of 6 pcs. 2.5 V xenon bulbs, May-ophthalmoscope uni®

11791 Vacuum Bulb 2.7 V

pen-scope, e-scope®

10488 Pack of 6 pcs. 2.7 V vacuum bulbs, for pen-scope and e-scope® otoscope

10473 Pack of 6 pcs. XL 2.5 V bulbs, pen-scope (same as ophthalmoscope)

Replacement lamps HL 2.5 V / XL 2.5V

uni®, econom®

10590 Pack of 6 pcs. XL 2.5 V bulbs, otoscope uni®

12600 Xenon bulb 3,5 V ophthalmoscope

11440 Bulb XL 2.5 V, Otoscope uni®

11860 Xenon bulb 2,5 V

12032 Xenon bulb 3,5 V

11442 Bulb XL 3.5 V otoscope uni®

pen-scope, ri-mini®, ri-scope® L, e-scope®

10489 Pack of 6 pcs. XL 2.5 V bulbs for otoscope pen-scope/ri-scope® L1 and e-scope®

10600 Pack of 6 pcs. XL 2.5 V bulbs, for otoscope ri-mini®, ri-scope® L2/L3 and e-scope®

10602 Pack of 6 pcs. HL 2.5 V bulbs, for operation otoscope (human/verterinary)

10605 Pack of 6 pcs. XL 2.5 V bulbs, for ophthalmoscope ri-mini®/ri-scope® L1, L2, L3,e-scope®,ri-derma

ri-scope® retinoscope

10615 Pack of 6 pcs. HL 2.5 V slit bulbs

e-xam

11178 Pack of 6 pcs. XL 2.5 V bulbs, ri-pen® H, e-xam

Replacement lamps xenon XL 3.5 V

uni®, econom®

10592 Pack of 6 pcs. XL 3.5 V bulbs, otoscope uni®

10593 Pack of 6 pcs. XL 3.5 V bulbs, May-ophthalmoscope uni®

ri-scope®

10487 Pack of 6 pcs. XL 3.5 V bulbs otoscope ri-scope® L1

10607 Pack of 6 pcs. XL 3.5 V bulbs, ri-scope® otoscope L2/L3

10608 Pack of 6 pcs. XL 3.5 V bulbs, ri-scope® ophthalmoscope L1, L2, L3

10609 Pack of 6 pcs. XL 3.5 V bulbs, operation otoscope (human/veterinary)

ri-scope® retinoscope

10610 Pack of 6 pcs. XL 3.5 V slit bulbs

10611 Pack of 6 pcs. XL 3.5 V spot bulbs

Replacement lamps LED 2.5/ 3.5 V

ri-scope®

- 10624 LED 2.5V for ri-scope® L ophthalmoscope L1/L2/L3 Kelvin = 4000, CRI = 92
- 10625 LED 3,5V for ri-scope® L otoscopes L2/L3/EliteVue Kelvin = 4000, CRI = 92
- 10626 LED 2.5 V for ri-scope® L otoscopes L2/L3, Kelvin = 4000, CRI = 92
- 10627 LED 3,5V bulb for ophthalmoscope ri-scope® L1/L2/L Kelvin = 4000, CRI = 92
- 12033 Xenon bulb 3,5 V ophthalmoscope

e-xam

- 12320 Bulb LED 2,5 V

e-scope®

- 14041 LED 3.7 V bulb for e-scope® F.O. otoscope
- 14051 Spare bulbs for e-scope® ophthalmoscope, LED 3,7V,

Instrument heads

uni®, econom® with pin contact

- 10420 Otoscope head vacuum 2.7 V, pin contact
- 10419 Otoscope head XL 2.5 V, pin contact
- 10418 Otoscope head XL 3.5 V, pin contact
- 10423 May-ophthalmoscope head XL 2.5 V, pin contact
- 10416 May-ophthalmoscope head XL 3.5 V, pin contact
- 10443 Bent arm illuminator vacuum 2.7 V, pin contact
- 10442 Bent arm illuminator XL 2.5 V, pin contact
- 10441 Bent arm illuminator XL 3.5 V, pin contact
- 10440 Nasal speculum, chrome plated
- 10445 Tongue blade holder
- 10447 1 pair of laryngeal mirrors

Instrument heads ri-scope® L/EliteVue 2.5 V (3.5 V see section Instrument heads ri-former®)

- 10510 EliteVue head only, LED, 2.5V
- 10511 EliteVue head only, XL, 2.5V
- 10597 ri-scope®L ophthalmoscope head L2 LED 2,5 V
- 10598 ri-scope® ophthalmoscope head L3 LED 2,5 V
- 10560 ri-scope® OP-otoscope head (human) HL 2.5 V
- 10541 ri-scope® OP-otoscope head (veterinary) HL 2.5 V
- 10561 ri-scope® OP-otoscope head (human) XL 3.5 V
- 10561-300 ri-scope® OP-otoscope head (human) XL 3.5 V, anti-theft proof
- 10562 ri-scope® L1 otoscope head XL 2.5 V
- 10534 ri-scope® F.O. tongue blade holder XL 2.5 V
- 10536 ri-scope® F.O. nasal speculum XL 2.5 V
- 10538 ri-scope® F.O. bent arm illuminator XL 2.5 V
- 10543 ri-scope® retinoscope head slit HL 2.5 V
- 10564 ri-scope® L2 F.O. otoscope head XL 2.5 V
- 10550 ri-derma dermatoscope head XL 2.5 V
- 10566 ri-scope® L3 F.O. otoscope head XL 2.5 V
- 10568 ri-scope® ophthalmoscope head L1 XL 2.5 V
- 10570 ri-scope® ophthalmoscope head L2 XL 2.5 V

10571 ri-scope® L Ophthalmoskopkopf L2 XL 3,5 V
10572 ri-scope® ophthalmoscope head L3 XL 2.5 V

Instrument heads ri-mini®

10502 ri-mini® F.O. otoscope head HL 2.5 V, black
10503 ri-mini® ophthalmoscope head HL 2.5 V, black

Swivel lenses

11449 Operation lens for ri-scope® L otoscope
10448 Swivel magnifying glass uni® otoscope, pin contact
11564 Swivel magnifying glass, nasal speculum ri-scope®

Magnifying lenses

10965 Separate magnifying glass ri-scope® ophthalmoscope

Battery handles

Battery handle type AA, Ø 19 mm for 2 batteries type AA

ri-former®/ri-scope® L with rheotronic®

10642 Handle Typ AA with rheotronic® for 2 batteries AA or 1 ri-accu®L
10659 AA type battery handle black, with coiled cable tubing, ri-former®

Battery handle type C, Ø 28 mm

uni®, econom® with pin contact

10425 C type battery handle, rheostat, chrome plated without bore, for 2 C cell batteries
10429 C type battery handle, rheostat, chrome plated, for 2 C cell batteries or 1 ri-accu®
10426 Upper handle part with rheostat, chrome plated

Battery handle cover

10679 Battery handle cover, chrome plated without bore
11682 Battery handle cover, chrome plated with bore

ri-scope® with bayonet fitting

10670 C type battery handle, rheotronic®, black chrome p for 2 C cell batteries or 1 ri-accu®

Charging base and accessories

10713 Cover for specula compartment for ri-charger®L
10707 Plug-in charger for Li-Ion rech. battery 3.5V ri-a for battery handle type C, with EU-plug
10708 Plug-in charger with Li-Ion rech. battery 3.5V ri- for battery handle type C, with EU-plug
10700 ri-charger® 2.5 V / 3.5 V / 100-240V, with wall support
10701 ri-charger® 2.5 V / 3.5 V / 100-240V, with wall support
10705 ri-charger® L 3,5 V,100-240 V, with wall support
10706 ri-charger® L 3.5 V / 100V-240V with wall support
10711 AA type handle insert ri-charger®
10710 Wall support ri-charger®, with screws and dowels
10712 Ear specula compartment cover ri-charger®
10704 USB handle type C with rechargeable battery and charger, EU

Batteries

Rechargeable batteries for battery handles rechargeable

10690 Lithium rechargeable battery 3,5V ri-accu®L for AA-type battery handle and ri-charger® L
10691 Lithium rechargeable battery 3,5V ri-accu®L for C-type battery handle and ri-charger® L
10694 Li-Ion rech. Battery 3.5V ri-accu® L for plug-in c for battery handle type C

- 10680 ri-accu® 2.5 V NiMH for AA type battery handles
10681 ri-accu® 2.5 V NiMH for C type battery handles

Quality batteries, non-rechargeable

for handles type AA

- 10685 4 pcs. AA type alkaline batteries, Mignon Type E 91 Alkaline 1.5 V

for handles type C

- 10686 2pc. C type batteries, "PROCELL", Duracell Alkaline 1.5 V, MV 1400 LR14

Reusable ear and nasal specula

uni®, econom® and ri-scope® operation otoscope (human), metal attachment

- 10460 Reusable ear specula Ø 2 mm, black, uni®, econom® etc.
10461 Reusable ear specula Ø 3 mm, black, uni®, econom® etc.
10462 Reusable ear specula Ø 4 mm, black, uni®, econom® etc.
10463 Reusable ear specula Ø 5 mm, black, uni®, econom® etc.
10464 Reusable nasal specula Ø9 mm, black, uni®, econom® etc.

pen-scope, ri-mini®, pocket instruments, ri-scope® L1/L2, e-scope®

- 10775 Pack of 10 pcs. reusable ear specula Ø 2.0 mm, bla ri-scope® L1/L2,pen-scope/ri-mini® and e-scope®
10779 Pack of 10 pcs. reusable ear specula Ø 2.5 mm, bla ri-scope® L1/L2,pen-scope/ri-mini® and e-scope®
10783 Pack of 10 pcs. reusable ear specula Ø 3.0 mm, bla ri-scope® L1/L2,pen-scope/ri-mini® and e-scope®
10789 Pack of 10 pcs. reusable ear specula Ø 4.0 mm, bla ri-scope® L1/L2,pen-scope/ri-mini® and e-scope®
10795 Pack of 10 pcs. reusable ear specula Ø 5.0 mm, bla ri-scope® L1/L2,pen-scope/ri-mini® and e-scope®

ri-scope®

- 10865 Pack of 100 pcs. disposable ear specula Ø 4.0 mm, grey, ri-scope®

ri-scope® L3

- 10800-532 Pack of 10 pcs. reusable ear specula Ø 2 mm, black, ri-scope® L3
10800-533 Pack of 10 pcs. reusable ear specula Ø 3 mm, black, ri-scope® L3
10800-534 Pack of 10 pcs. reusable ear specula Ø 4 mm, black, ri-scope® L3
10800-535 Pack of 10 pcs. reusable ear specula Ø 5 mm, black, ri-scope® L3
10800-539 Pack of 10 pcs. reusable nasal specula Ø 9 mm, black, ri-scope® L3

Disposable ear and nasal specula

pen-scope, ri-mini®, pocket instruments, ri-scope® L1/L2

- 10772-531 Pack of 100 pcs. disposable ear specula Ø 2,5 mm, ri-scope® L1/L2 and pen-scope/ri-mini®
10772-532 Pack of 100 pcs. disposable ear specula Ø 2 mm, ri-scope® L1/L2 and pen-scope/ri-mini®
10772-533 Pack of 100 pcs. disposable ear specula Ø 3 mm, ri-scope® L1/L2 and pen-scope/ri-mini®
10772-534 Pack of 100 pcs. disposable ear specula Ø 4 mm, ri-scope® L1/L2 and pen-scope/ri-mini®
10772-535 Pack of 100 pcs. disposable ear specula Ø 5 mm, ri-scope® L1/L2 and pen-scope/ri-mini®
10773-531 Pack of 500 pcs. disposable ear specula Ø 2,5 mm, ri-scope® L1/L2
10773-532 Pack of 500 pcs. disposable ear specula Ø 2 mm, ri-scope® L1/L2
10773-533 Pack of 500 pcs. disposable ear specula Ø 3 mm, for ri-scope® L1/L2 und pen-scope/ri-mini®
10773-534 Pack of 500 pcs. disposable ear specula Ø 4 mm, ri-scope® L1/L2
10773-535 Pack of 500 pcs. disposable ear specula Ø 5 mm, ri-scope® L1/L2

- 10774-531 Pack of 1000 pcs. disposable ear specula Ø 2,5 mm, ri-scope® L1/L2
- 10774-532 Pack of 1000 pcs. disposable ear specula Ø 2 mm, ri-scope® L1/L2
- 10774-533 Pack of 1000 pcs. disposable ear specula Ø 3 mm, ri-scope® L1/L2
- 10774-534 Pack of 1000 pcs. disposable ear specula Ø 4 mm, , ri-scope® L1/L2
- 10774-535 Pack of 1000 pcs. disposable ear specula Ø 5 mm, ri-scope® L1/L2
- 12611 Tube with speculas for ri-scope®L1/L2

ri-scope® L3 + EliteVue

- 10801-532 Pack of 100 pcs. disposable ear specula Ø 2 mm, ri-scope® L3
- 10801-533 Pack of 100 pcs. disposable ear specula Ø 3 mm, ri-scope® L3
- 10801-534 Pack of 100 pcs. disposable ear specula Ø 4 mm, ri-scope® L3
- 10801-535 Pack of 100 pcs. disposable ear specula Ø 5 mm, ri-scope® L3
- 10801-539 Pack of 100 pcs. disposable nasal specula Ø 9 mm, ri-scope® L3
- 10802-532 Pack of 500 pcs. disposable ear specula Ø 2 mm, ri-scope® L3
- 10802-533 Pack of 500 pcs. disposable ear specula Ø 3 mm, ri-scope® L3
- 10802-534 Pack of 500 pcs. disposable ear specula Ø 4 mm, ri-scope® L3
- 10802-535 Pack of 500 pcs. disposable ear specula Ø 5 mm, ri-scope® L3
- 10802-539 Pack of 500 pcs. disposable nasal specula Ø 9 mm, black, ri-scope® L3
- 10803-532 Pack of 1000 pcs. disposable ear specula Ø 2 mm, ri-scope® L3
- 10803-533 Pack of 1000 pcs. disposable ear specula Ø 3 mm, ri-scope® L3
- 10803-534 Pack of 1000 pcs. disposable ear specula Ø 4 mm, , ri-scope® L3
- 10803-535 Pack of 1000 pcs. disposable ear specula Ø 5 mm, ri-scope® L3
- 10803-539 Pack of 1000 pcs. reusable nasal specula Ø 9 mm, ri-scope® L3

e-scope®

- 14061-531 Pack of 100 pcs. disposable speculas Ø 2.5 mm, bla for e-scope® + ri-scope®otoscope L1+L2
- 14061-532 Pack of 100 pcs. disposable specula Ø 2 mm, black, for e-scope® + ri-scope®otoscope L1+L2
- 14061-533 Pack of 100 pcs. disposable specula Ø 3 mm, black, for e-scope®+ ri-scope®otoscope L1+L2
- 14061-534 Pack of 100 pcs. disposable speculas, Ø 4 mm, blac for e-scope®+ ri-scope®otoscope L1+L2
- 14061-535 Pack of 100 pcs. disposable specuals, Ø 5 mm, blac for e-scope® + ri-scope®otoscope L1+L2
- 14062-531 Pack of 500 pcs. disposable specuals Ø 2.5 mm, bla for e-scope®
- 14062-532 Pack of 500 pcs. disposable specuals Ø 2 mm, black for e-scope®
- 14062-533 Pack of 500 pcs. disposable specuals Ø 3 mm, black for e-scope®
- 14062-534 Pack of 500 pcs. disposable specuals Ø 4 mm, black for e-scope®
- 14062-535 Pack of 500 pcs. disposable specuals Ø 5 mm, black for e-scope®
- 14063-531 Pack of 1000 pcs. disposable specuals Ø 2.5 mm, bl for e-scope®
- 14063-532 Pack of 1000 pcs. disposable specuals Ø 2 mm, blac for e-scope®
- 14063-533 Pack of 1000 pcs. disposable specuals Ø 3 mm, blac for e-scope®
- 14063-534 Pack of 1000 pcs. disposable specuals Ø 4 mm, blac for e-scope®
- 14063-535 Pack of 1000 pcs. disposable specuals Ø 5 mm, blac for e-scope®

for ri-former® specula dispenser, otoscopes ri-scope® L1/L2/L3

- 14065-531 Pack of 1000pcs, 40x25pcs in plastic sleeves, disp speculas Ø 2,5mm, black for ri-scope® L1/L2
- 14065-534 Pack of 1000pcs, 40x25pcs in plastic sleeves, disp speculas Ø 4,0mm, black for ri-scope® L1/L2

14066-532 Pack with 1000 pcs., 40x25 pieces in polybag disposable ear speculaes for ri-scope®L3 Ø 2.0 mm

14066-534 Pack with 1000 pcs., 40x25 pieces in polybag disposable ear speculaes for ri-scope®L3 Ø 4.0 mm

Bulb and connector for pneumatic test

10960 Bulb for pneumatic test

10961 Connector for pneumatic test

Eye tonometers

11129 Weight 5.5 g, Schiötz

11130 Weight 7.5 g, Schiötz

11131 Weight 10 g, Schiötz

11132 Weight 15 g, Schiötz

11133 Button Schiötz

Binocular loupes

12760 Protective caps SuperVu Galilean System

12761 Protective caps for SuperVu Hi-Res Galilean System

12762 +1D close-up and distance cap for SuperVu Galilean System

12763 +1D close-up and distance cap for Hi-Res Galilean system

12765 K-L.E.D. System with charger

12770 Black spectacle frame without loupe

12771 Brow band without loupe