

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY



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

Produktfamilie /
Product family: **Stethoskop, mechanisch**
Stethoscopes, Mechanical

Zweckbestimmung /
Intended use: Diagnostikinstrument zur Auskultation (Abhören) der Herztöne/ -geräusche,
der Lungengeräusche sowie anderer hörbarer vitaler Parameter.
Diagnostic instrument for auscultation (listening) of heart sounds, lung sounds
and other audible vital parameters.

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.

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.

Basis UDI-DI / Basic UDI-DI: 4030155KaWe06SU

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

Asperg, 2021-04-27

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
Stethoskop, mechanisch

List of devices accompanying the declaration of conformity
Stethoscopes, Mechanical

<u>Artikel-Nr. / Ref</u>	<u>Bezeichnung</u>	<u>Denomination</u>
06.10100.014	Colorescop-Steth. "Plano" rot	Colorescop-plano stethoscope red
06.10100.024	Colorescop-Steth. "Plano" schwarz	Colorescop-plano stethoscope black
06.10100.034	Colorescop-Steth. "Plano" blau	Colorescop-plano stethoscope blue
06.10100.044	Colorescop-Steth. "Plano" grün	Colorescop-plano stethoscope green
06.10100.054	Colorescop-Steth. "Plano" gelb	Colorescop-plano stethoscope yellow
06.10100.094	Colorescop-Steth. "Plano" lila	Colorescop-plano stethoscope violet
06.10100.124	Colorescop-Steth. "Plano" türkis	Colorescop-plano stethoscope turquoise
06.10100.134	Colorescop-Steth. "Plano" pink	Colorescop-plano stethoscope pink
06.10300.012	Flachkopf-Stethoskop single rot, Aluminium	Nurse stethoscope single red, aluminium
06.10300.022	Flachkopf-Stethoskop single schwarz, Aluminium	Nurse stethoscope single black, aluminium
06.10300.032	Flachkopf-Stethoskop single blau, Aluminium	Nurse stethoscope single blue, aluminium
06.10800.022	Top-Kardiologie Stethoskop, Edelstahl, schwarz	Top Cardiology stethoscope stainlesssteel, black
06.10800.172	Top-Kardiologie Stethoskop Edelstahl, burgunder	Top Cardiology stethoscope stainlesssteel, burgundy
06.22100.014	Colorescop-Steth. "Duo" rot	Colorescop-duo stethoscope red
06.22100.024	Colorescop-Steth. "Duo" schwarz	Colorescop-duo stethoscope black
06.22100.034	Colorescop-Steth. "Duo" blau	Colorescop-duo stethoscope blue

06.22100.044	Colorscop-Steth. "Duo" grün	Colorscop-duo stethoscope green
06.22100.054	Colorscop-Steth. "Duo" gelb	Colorscop-duo stethoscope yellow
06.22100.094	Colorscop-Steth. "Duo" lila	Colorscop-duo stethoscope violet
06.22100.124	Colorscop-Steth. "Duo" türkis	Colorscop-duo stethoscope turquoise
06.22100.134	Colorscop-Steth. "Duo" pink	Colorscop-duo stethoscope pink
06.22300.012	Doppelkopf-Stethoskop double rot, Aluminium	Double twin-head stethoscope red, aluminium
06.22300.022	Doppelkopf-Stethoskop double schwarz, Aluminium	Double twin-head stethoscope black, aluminium
06.22300.032	Doppelkopf-Stethoskop double blau, Aluminium	Double twin-head stethoscope blue, aluminium
06.22500.012	Rapport-Stethoskop kpl., mit Ersatzteil-Set, rot	Stethoscope Rapport, cpl., with various funnels, red
06.22500.022	Rapport-Stethoskop kpl., mit Ersatzteil-Set, schwarz	Stethoscope Rapport, cpl., with various funnels, black
06.22500.032	Rapport-Stethoskop kpl. mit Ersatzteil-Set, blau	Stethoscope Rapport, cpl. with various funnels, blue
06.22500.042	Rapport-Stethoskop, kpl. mit Ersatzteil-Set, grün	Stethoscope Rapport, cpl., with various funnels, green
06.22500.092	Rapport-Stethoskop kpl. mit Ersatzteil-Set, lila	Stethoscope Rapport, cpl., with various funnels, violett
06.22500.122	Rapport Stethoskop black line	Stethoscope Rapport black line
06.22700.012	Standard-Prestige-Stethoskop Edelstahl, rot	Standard-Prestige stethoscope stainlesssteel, red
06.22700.022	Standard-Prestige-Stethoskop Edelstahl, schwarz	Standard-Prestige stethoscope stainlesssteel, black
06.22700.032	Standard-Prestige-Stethoskop Edelstahl, blau	Standard-Prestige stethoscope stainlesssteel, blue
06.22700.042	Standard-Prestige-Stethoskop Edelstahl, grün	Standard-Prestige stethoscope stainlesssteel, green
06.22700.092	Standard-Prestige-Stethoskop Edelstahl, lila	Standard-Prestige stethoscope stainlesssteel, violet

06.22700.172	Standard-Prestige-Stethoskop Edelstahl, burgunder	Standard-Prestige stethoscope stainlesssteel, burgundy
06.22700.262	Standard-Prestige-Stethoskop Edelstahl, grau	Standard-Prestige stethoscope stainlesssteel, grey
06.22701.012	Baby-Prestige Stethoskop Edelstahl, rot	Baby-Prestige stethoscope stainlesssteel, red
06.22701.022	Baby-Prestige Stethoskop Edelstahl, schwarz	Baby-Prestige stethoscope stainlesssteel, black
06.22701.032	Baby-Prestige Stethoskop Edelstahl, blau	Baby-Prestige stethoscope stainlesssteel, blue
06.22701.042	Baby-Prestige Stethoskop Edelstahl, grün	Baby-Prestige stethoscope stainlesssteel, green
06.22701.092	Baby-Prestige Stethoskop Edelstahl, lila	Baby-Prestige stethoscope stainlesssteel, violet
06.22701.172	Baby-Prestige Stethoskop Edelstahl, burgunder	Baby-Prestige stethoscope stainlesssteel, burgundy
06.22701.262	Baby-Prestige Stethoskop Edelstahl, grau	Baby-Prestige stethoscope stainlesssteel, grey
06.22702.012	Kinder-Prestige Stethoskop Edelstahl, rot	Children-Prestige stethoscope stainlesssteel, red
06.22702.022	Kinder-Prestige Stethoskop Edelstahl, schwarz	Children-Prestige stethoscope stainlesssteel, black
06.22702.032	Kinder-Prestige Stethoskop Edelstahl, blau	Children-Prestige stethoscope stainlesssteel, blue
06.22702.042	Kinder-Prestige Stethoskop Edelstahl, grün	Children-Prestige stethoscope stainlesssteel, green
06.22702.092	Kinder-Prestige Stethoskop Edelstahl, lila	Children-Prestige stethoscope stainlesssteel, violet
06.22702.172	Kinder-Prestige Stethoskop Edelstahl, burgunder	Children-Prestige stethoscope stainlesssteel, burgundy
06.22702.262	Kinder-Prestige Stethoskop Edelstahl, grau	Children-Prestige stethoscope stainlesssteel, grey
06.22710.012	Standard-Prestige light Stethoskop, Aluminium, rot	Standard-Prestige light stethoscope, aluminium, red
06.22710.022	Standard-Prestige light Stethoskop, Aluminium, schwarz	Standard-Prestige light stethoscope, aluminium, black
06.22710.042	Standard-Prestige light Stethoskop, Aluminium, grün	Standard-Prestige light stethoscope, aluminium, green

06.22710.092	Standard-Prestige light Stethoskop, Aluminium, lila	Standard-Prestige light stethoscope, aluminium, violet
06.22710.232	Standard-Prestige light Stethoskop, Aluminium, blau	Standard-Prestige light stethoscope, aluminium, blue
06.22710.262	Standard-Prestige light Stethoskop, Aluminium, grau	Standard-Prestige light stethoscope, aluminium, grey
06.22711.012	Baby-Prestige light Stethoskop, Aluminium,rot	Baby-Prestige light stethoscope, aluminium, red
06.22711.022	Baby-Prestige light Stethoskop, Aluminium, schwarz	Baby-Prestige light stethoscope, aluminium, black
06.22711.042	Baby-Prestige light Stethoskop, Aluminium, grün	Baby-Prestige light stethoscope, aluminium, green
06.22711.092	Baby-Prestige light Stethoskop, Aluminium, lila	Baby-Prestige light stethoscope, aluminium, violet
06.22711.232	Baby-Prestige light Stethoskop, Aluminium, blau	Baby-Prestige light stethoscope, aluminium, blue
06.22711.262	Baby-Prestige light Stethoskop, Aluminium, grau	Baby-Prestige light stethoscope, aluminium, grey
06.22712.012	Kinder-Prestige light Stethoskop, Aluminium, rot	Children-Prestige light stethoscope, aluminium, red
06.22712.022	Kinder-Prestige light Stethoskop, Aluminium, schwarz	Children-Prestige light stethoscope, aluminium, black
06.22712.042	Kinder-Prestige light Stethoskop, Aluminium, grün	Children-Prestige light stethoscope, aluminium, green
06.22712.092	Kinder-Prestige light Stethoskop, Aluminium, lila	Children-Prestige light stethoscope, aluminium, violet
06.22712.232	Kinder-Prestige light Stethoskop, Aluminium, blau	Children-Prestige light stethoscope, aluminium, blue
06.22712.262	Kinder-Prestige light Stethoskop, Aluminium, grau	Children-Prestige light stethoscope, aluminium, grey
06.22800.022	Profi-Kardiologie-Stethoskop Edelstahl, schwarz	Profi-Cardiology stethoscope stainlesssteel, black
06.22800.172	Profi-Kardiologie-Stethoskop Edelstahl, burgunder	Profi-Cardiology stethoscope stainlesssteel, burgundy
06.22900.022	Planet-Hochleistungs- Stethoskop nach Fassbender	Planet double stethoscope accordingto Fassbender
06.22910.122	Planet Air Stethoskop	Planet Air stethoscope

06.34100.144	Schwestern-Lehr-Steth. mit 2 Ohrbügel "Plano" rot	Nurse teaching stethoscope, with 2 binaurals "plano" red
06.34200.144	Schwestern-Lehr-Steth. mit 2 Ohrbügel "Duo" rot	Nurse teaching stethoscope with 2 binaurals "duo" red
06.46117.001	Stethoskop nach PINARD aus Buchenholz, 17 cm	Stethoscope according Pinard of beech wood 17 cmlength
06.46133.001	Stethoskop nach Pinard aus Buchenholz, 33 cm	Stethoscope acc. Pinard beech wood, 33cm
06.46201.182	Petiphon-Stethoskop mit Ohrbügel	Petiphon stethoscope with binaural
06.46300.182	Multiphon-Stethoskop kpl. mit Ohrbügel	Multiphonstethoscope complete with binaural
06.91111.021	Ohr-Oliven, schwarz, D. 5,5 mm VE = 10 St. m. weißen Drehteilen	Ear tips, black, Ø 5,5 mm, PU: 10 pcs. W. white turned parts
06.91120.021	Ohr-Oliven weich, schwarz innen D. 5 mm VE = 10 Stück	Ear tips, soft plastic, black inside Ø 5 mm pack.= 10 pcs.
06.91210.021	Ohr-Olive soft, schraubbar VE = 10 St., schwarz	Ear-tips soft, screwable PU = 10 pcs., black
06.91220.021	Ohr-Olive soft, schraubbar VE = 10 St., schwarz	Ear-tips soft, screwable PU = 10 items, black
06.92100.001	Ohrbügel klein, Rohr 5 mm Durchmesser	Binaural,small, tube Ø 5 mm
06.92400.001	Ohrbügel zusammenlegbar, 7 mm für schwarze Schläuche	Binaural,collapsible, tube Ø 7 mm, forblack tubes
06.93154.011	Y-Schlauch rot, 55 cm lang	Stethoscope Y-tube, red length 55cm
06.93154.021	Y-Schlauch, schwarz, ca. 55 cm lang	Stethoscope Y-tube, black length 55cm
06.93154.031	Y-Schlauch blau, 55 cm lang	Stethoscope Y-tube, blue length 55cm
06.93154.041	Y-Schlauch grün, 55 cm lang	Stethoscope Y-tube, green length 55cm
06.93154.051	Y-Schlauch gelb, 55 cm lang	Stethoscope Y-tube, yellow length 55cm
06.93154.091	Y-Schlauch lila, 55 cm lang	Stethoscope Y-tube, violet length 55cm
06.93154.121	Y-Schlauch türkis, 55 cm lang	Stethoscope Y-tube, turquoise length 55cm

06.93154.131	Y-Schlauch pink, 55 cm lang	Stethoscope Y-tube, pink length 55cm
06.93265.021	Doppelschlauch schwarz 60 cm lang	Stethoscope double tube, black length 60cm
06.93275.021	Doppelschlauch schwarz 75 cm lang	double tube for stethoscopes black, length 75 cm
06.93294.021	Doppelschlauch schwarz pro Meter	Stethoscope double tube, black per meter

Double Stethoskop | Double Stethoscope

ALUMINIUM-BRUSTSTÜCK | ALUMINIUM CHEST PIECE

Das Double Doppelkopf-Stethoskop ist die preiswerte Alternative zum KaWe COLORSCOP Duo. Das Bruststück ist aus Aluminium gefertigt und daher besonders leicht.

The Double dual-head stethoscope is the less expensive alternative to the KaWe COLORSCOP Duo. The chest piece is made of aluminium and is therefore especially lightweight.

Double-Stethoskop Double stethoscope

- Doppelkopf-Stethoskop, umschaltbar
- Aluminium-Bruststück
- Membrane Ø 43,8 mm
- Gesamtlänge ca. 80 cm
- leichtes Eigengewicht: ca. 102 gr.
- dual-head stethoscope, reversible
- aluminium chest piece
- diaphragm Ø 43.8 mm
- total length approx. 80 cm
- lightweight: approx. 102 gr.

rot | red  REF 06.22300.012

schwarz | black  REF 06.22300.022

blau | blue  REF 06.22300.032



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Rapport Stethoskop | Rapport Stethoscope

Das Rapport Doppelkopf-Stethoskop mit seiner ausgezeichneten Akustik hat sich seit Jahren bewährt. In verschiedenen Farben lieferbar ist dieses Stethoskop besonders bei Studenten äußerst beliebt. Ein umfangreiches Ersatzteil-Set liegt jedem Stethoskop bei.

The Rapport dual-head stethoscope with its excellent acoustics has been proving its worth for years. This stethoscope is extremely popular among students because it is available in many different colours. Each stethoscope comes with an extensive set of spare parts.

Rapport-Stethoskop Rapport stethoscope

- Doppelkopf-Stethoskop, umschaltbar
- Membran Ø 40 mm
- Gesamtlänge ca. 72 cm
- inkl. umfangreichem Ersatzteil-Set
- Gewicht: ca. 216 gr.
- dual-head stethoscope, reversible
- diaphragm Ø 40 mm
- total length approx. 72 cm
- incl. a large spare parts set
- weight: approx. 216 gr.

rot | red  REF 06.22500.012

schwarz | black  REF 06.22500.022

blau | blue  REF 06.22500.032

grün | green  REF 06.22500.042

lila | violet  REF 06.22500.092



ERSATZTEILE | SPARE PARTS

Rapport-Ersatzteil-Etui | Rapport spare parts case

- 2 Paar Ohroliven
- 3 Aufsatztrichter
- Ø 19,5 / 26,0 / 33,0 mm
- 2 Membranen
- 1 Schlüssel
- 2 pairs of ear tips
- 3 attachment funnels,
- Ø 19.5 / 26.0 / 33.0 mm
- 2 diaphragms
- 1 wrench



nur als Set erhältlich | available only as a set

REF 06.99250.001

112342

CERTIFICATE

No. 490346



This is to certify the Quality Management System of Medical Devices of



KIRCHNER & WILHELM GmbH + Co. KG

Eberhardstr. 56
71679 Asperg
Germany

has been assessed and found to be in compliance with the Standard

ISO 13485:2016

applicable to

**Development, production and sales of medical devices for
general medicine, otolaryngology, ophthalmology,
anesthesiology and dermatology.**

The certificate has been issued under No. **490346** for the registration period
from 16 November 2020 to 15 November 2023.
The first certificate date of issue is 16 November 2017.


Approved by


Printed by



validity code **11244C52-6E6**

Check the validity of this certificate using this code at www.ll-c.info





EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-128

Issued to: Kirchner & Wilhelm GmbH + Co. KG
Eberhardstrasse 56, 71679 ASPERG, Germany
Product category: Blood pressure measuring devices
UMDNS: 16-156

SIQ has audited the quality system in accordance with MDD Annex V, restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on:

Audit report No.:

OSV 00357B/2019, 2019-04-11
OSV 00022/2019, 2019-02-25
OSV 01182/2018, 2018-10-29
OSV 00984/2018, 2018-08-30
OSV 00921/2018, 2018-08-20

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4), restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and continues to meet the above requirements.

Certification date: 2019-04-04

Issue: 2/2019-04-12

Valid until: 2024-04-04



Director of SIQ

Igor Likar