CONTENITORI FRIGO PER TRASPORTO

Realizzati in materiale antiurto (PE, PP, PVC) con isolamento termico che permette di conservare il freddo. Omologati per alimenti e quindi garantiti completamente atossici. Il manico pieghevole integrato facilita lo stoccaggio. Utilizzabili con unità ghiaccio. Resistenza alle temperature: min. - 50°C max + 80°C.

Cod.	Descrizione	Dim. mm	Vol. lt	TDS
6900	Contenitore	380 x 260 x 310	15	
6550	Tavoletta refrigerante	95 x 40 x 180	0,5	
6560	Tavoletta refrigerante	115 x 50 x 220	1	

Digitally signed by Ceaicovschi Tudor
Date: 2022.08.18 10:14:37 EEST
Reason: MoldSign Signature
Location: Moldova

SAFETY BOX

Contenitore per trasporto campioni, realizzato in policarbonato e completamente autoclavabile. Il coperchio è dotato di guarnizione ermetica in silicone, tale da garantire un elevato standard di sicurezza, anche in caso di fuoriuscite accidentali di fluidi contenuti all'interno, ed è provvisto di n°4 ganci che impediscono l'apertura del contenitore in caso di caduta. Completo di manico in acciaio inox e scheda di utilizzo con istruzioni. Simbolo di rischio biologico impresso sul coperchio. Disponibile anche il supporto per safety box in acciaio inox. Progettato per 10 contenitori urine fino a 200 ml e 4 contenitori feci da 30 ml.

Cod.	Descrizione	Dim. mm
10731	Safety box	330 x 175 x 180
10732	Rack	322 x 145 x 60

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
Otoscopes

Artikel-Nr. / Ref	Bezeichnung	Denomination
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. LiIon (C)	EUROLIGHT F.O.30 otoscope incl. charg. battery LiIon(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 LiIon (C)	COMBILIGHT F.O.30 otoscope incl. charg. battery LiIon (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 Otoskop, stone mit Ohrtrichtern, Stofftasche	PICCOLIGHT C otoscope, stone with ear funnels, cloth bag
01.13300.021	PICCOLIGHT F.O. Otoskop night mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O. otoscope night, ear funnels,cloth bag
01.13300.232	PICCOLIGHT F.O. Otoskop, sky mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O. otoscope, sky with ear funnels, cloth bag
01.13300.262	PICCOLIGHT F.O.Otoskop, stone mit Ohrtrichtern, Stofftasche	PICCOLIGHT F.O.otoscope,stone with ear funnels, cloth bag
01.13500.021	PICCOLIGHT F.O. LED standard, Otoskop, night,	PICCOLIGHT F.O. LED standard, otoscope,night,
01.13500.232	PICCOLIGHT F.O. LED standard, Otoskop, sky,	PICCOLIGHT F.O. LED standard, otoscope,sky,
01.13500.262	PICCOLIGHT F.O. LED standard, Otoskop, stone,	PICCOLIGHT F.O. LED standard, otoscope,stone,
01.13600.022	PICCOLIGHT F.O. LED high power, Otoskop, night,	PICCOLIGHT F.O. LED high power, otoscope, night,
01.13600.232	PICCOLIGHT F.O. LED high power, Otoskop, sky,	PICCOLIGHT F.O. LED high power, otoscope, sky,
01.13600.262	PICCOLIGHT F.O. LED high power, Otoskop, stone,	PICCOLIGHT F.O. LED high power, otoscope, stone,
01.73320.021	Otoskop-Kopf, XL, allein, night, zu PICCOLIGHT C, 3,5V	Otoscope head, XL, only, night, for PICCOLIGHT C, 3.5V
01.73550.021	Otoskop-Kopf, allein, night zu PICCOLIGHT F.O.LED high	Otoscope head, only, night to PICCOLIGHT F.O.LEDhigh
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 Otoskop	BASIC-SET COMBILIGHT C10 otoscope
02.01008.002	BASIC-SET COMBILIGHT C10/E15 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E15 ophthalmoscope and otoscope
02.01104.002	BASIC-SET COMBILIGHT C10/E16 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E16 ophthalmoscope and otoscope
02.11001.002	BASIC-SET COMBILIGHT C10/E10 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E10 ophthalmoscope and otoscope
02.11002.001	EUROLIGHT C10/E10 SET Ophthalmoskop und Otoskop	EUROLIGHTC10/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	EUROLIGHTF.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), (LiIon)	Rechargeable battery, medium Lithium-Ion, 3.5 V (C),(LiIon)

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Spekulum, Ohr** Specula, ear
Zweckbestimmung / Intended use:	Zubehör für die Otoskope von KaWe. Ermöglichen als Aufsatz die medizinische Untersuchung des äußeren Gehörgangs bis zum Trommelfell. Accessories for KaWe otoscopes. Enable medical examination of the external auditory canal up to the eardrum as an attachment.

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: 4030155KaWe0101YR

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

Asperg, 2021-04-27

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte

Spekulum, Ohr

List of devices accompanying the declaration of conformity

Specula, ear

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
01.71111.002	Ohrtrichter, klein, schwarz, Ø 2,5 mm, VE = 1000 St.	Ear funnel, black, small Ø 2,5 mm, PU = 1000 pcs.
01.71112.001	Ohrtrichter, klein, schwarz, 2,5 mm Ø, 100 St. weise verp.	Ear funnel, black, small Ø 2,5 mm, in units of 100 pcs.
01.71121.002	Ohrtrichter, groß, schwarz, Ø 4,0 mm, VE = 1000 St.	Ear funnel, black, large Ø 4,0 mm, PU = 1000 pcs.
01.71122.001	Ohrtrichter, groß, schwarz, Ø 4,0 mm, 100 St. weise verp.	Ear funnel, black, large Ø 4,0 mm, in units of 100 pcs.
01.71211.002	Ohrtrichter, klein, grau Ø 2,5 mm, VE = 1000 St.	Ear funnel, grey, small, Ø 2,5 mm, PU = 1000 pcs.
01.71212.001	Ohrtrichter, klein, grau,Ø 2,5 mm,10 x 100 St. im Polybeutel	Ear funnel, grey, small Ø 2,5 mm, 10 x 100 pcs. in polybag
01.71212.002	Ohrtrichter, klein,grau, Ø 2,5 mm, 10 x 100 St. im Karton	Ear funnel, small, grey, Ø 2,5 mm, 10 x 100 pcs. in carton
01.71221.002	Ohrtrichter groß, grau, Ø 4,0 mm, VE = 1000 St.	Ear funnel, grey, large, Ø 4,0 mm, PU = 1000 pcs.
01.71222.001	Ohrtrichter, groß,grau, Ø 4,0 mm, 10 x100 St. im Polybeutel	Ear funnel, grey, large Ø 4,0 mm, 10x100 pcs. in polybag
01.71222.002	Ohrtrichter, groß,grau, Ø 4,0 mm, 10 x 100 St. im Karton	Ear funnel, large, grey, Ø 4,0 mm, 10 x 100 pcs. in carton
01.72101.001	Ohrtrichter, wiederverwendbar, SET, Ø 2,5, 3,5, 4,5 mm,	Ear funnel-SET, Ø 2,5, 3,5, 4,5 mm, PU= 3 pcs.
01.72102.001	Ohrtrichter, wiederverwendbar, Ø 2,5 mm, VE = 3 Stück	Ear funnel, Ø 2,5 mm PU = 3 pcs.
01.72103.001	Ohrtrichter, wiederverwendbar, Ø 3,5 mm, VE = 3 Stück	Ear funnel, Ø 3,5 mm PU = 3 pcs.
01.72104.001	Ohrtrichter, wiederverwendbar, Ø 4,5 mm, VE = 3 Stück	Ear funnel, Ø 4,5 mm PU = 3 pcs.
01.72106.001	Ohrtrichter, wiederverwendbar, SET Ø 2,5/3,5/4,5/5,5/9,0 mm	Ear funnels, reusable, SET Ø 2,5/3,5/4,5/5,5/9,0 mm
01.72210.001	Ohrtrichter Set Ø 2,0/2,5/3,0/4,0/5,0 mm	Reusable ear funnels Set Ø 2,0/2,5/3,0/4,0/5,0 mm

01.72212.001	Ohrtrichter, wiederverwendbar, Ø 2,5 mm, 10 St.	Reusable ear funnels, Ø 2,5 mm, 10 pcs.
01.72213.001	Ohrtrichter, wiederverwendbar, Ø 4,0 mm, 10 St.	Reusable ear funnels, Ø 4,0 mm, 10 pcs.
01.72214.001	Ohrtrichter, wiederverwendbar, Ø 2,0 mm, 10 St.	Reusable ear funnels, Ø 2,0 mm, 10 pcs.
01.72215.001	Ohrtrichter, wiederverwendbar, Ø 3,0 mm, 10 St.	Reusable ear funnels, Ø 3,0 mm, 10 pcs.
01.72216.001	Ohrtrichter, wiederverwendbar, Ø 5,0 mm, 10 St.	Reusable ear funnels, Ø 5,0 mm, 10 pcs.

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Ophthalmoskop, direkt** Ophthalmoscopes, direct
Zweckbestimmung / Intended use:	Diagnostikinstrument für die optische Untersuchung des Augenhintergrundes mittels direkter Ophthalmoskopie. Für Sets gilt zusätzlich die Konformitätserklärung "Otoskope". Diagnostic instrument for optical examination of the fundus of the eye by direct ophthalmoscopy. For sets, the declaration of conformity "Otoscopes" 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: 4030155KaWe0102YT

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
Ophthalmoskop, direkt

List of devices accompanying the declaration of conformity
Ophthalmoscopes, direct

Artikel-Nr. / Ref	Bezeichnung	Denomination
01.21100.001	EUROLIGHT E10, 2,5V Ophthal-moskop mit Schraubgewinde	EUROLIGHT E10,2.5V ophthal-moscope with srew thread
01.21155.001	EUROLIGHT E15, 2,5V Ophthal-moskop mit Schraubgewinde	EUROLIGHT E15,2.5V ophthal-moscope with srew thread
01.21300.001	EUROLIGHT E30, 2,5V Ophthal-moskop mit Clic-Verschluss	EUROLIGHT E30, 2.5V ophthal-moscope with clic-closure
01.21361.001	EUROLIGHT E36, 2,5V Ophthal-moskop, EU-Version	EUROLIGHT E36, 2.5V ophthal-moscope, EU-version
01.21366.001	EUROLIGHT E36, 2,5V Ophthal-moskop, USA-Version	EUROLIGHT E36, 2.5V ophthal-moscope, USA-version
01.23500.021	PICCOLIGHT E50, 2,5V Ophthal-moskop, night,in Stofftasche	PICCOLIGHT E50, 2.5V Ophthal-moscope, night, in cloth bag
01.23500.231	PICCOLIGHT E50, 2,5V Ophthal-moskop, sky, in Stofftasche	PICCOLIGHT E50, 2.5V Ophthal-moscope, sky, in cloth bag
01.23500.261	PICCOLIGHT E50, 2,5V Ophthal-moskop, stone, in Stofftasche	PICCOLIGHT E50, 2.5V Ophthal-moscope, stone, in cloth bag
01.23555.031	PICCOLIGHT E55, 2,5V Ophthal-moskop, blau, 5 Blenden	PICCOLIGHT E55, 2.5V Ophthal-moscope, blue, 5 diaphragms
01.23555.041	PICCOLIGHT E55 2,5V, Ophthal-moskop, grün, 5 Blenden	PICCOLIGHT E55, 2.5V Ophthal-moscope, green, 5 diaphragms
01.23555.231	PICCOLIGHT E55, 2,5V Ophthal-moskop, sky, 5 Blenden	PICCOLIGHT E55, 2.5V Ophthal-moscope, sky, 5 diaphragms
01.23561.021	PICCOLIGHT E56, 2,5V Ophthal-moskop, night, Grünfilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, night, green filter
01.23561.231	PICCOLIGHT E56, 2,5V Ophthal-moskop, sky, Grünfilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, sky, greenfilter
01.23561.261	PICCOLIGHT E56, 2,5V Ophthal-moskop, stone, Grünfilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, stone, green filter
01.23566.021	PICCOLIGHT E56, 2,5V Ophthal-moskop, night, Blaufilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, night, blue filter
01.23566.231	PICCOLIGHT E56, 2,5V Ophthal-moskop, sky, Blaufilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, sky, blue filter

01.23566.261	PICCOLIGHT E56, 2,5V Ophthal-moskop, stone, Blaufilter,	PICCOLIGHT E56, 2.5V Ophthal-moscope, stone, blue filter
01.24355.002	EUROLIGHT E35, 2,5V Ophthal-moskop, LED	EUROLIGHT E35, 2.5V ophthal-moscope, LED
01.24361.001	EUROLIGHT E36, 2,5V Ophthal-moskop, EU-Version, LED	EUROLIGHT E36, 2.5V ophthal-moscope, EU-version, LED
01.25361.101	EUROLIGHT E36, 3,5V Ophthal-moskop, inkl. LiIon Ladebatterie	EUROLIGHT E36, 3.5V ophthal-moscope, incl. LiIon charge battery
01.25361.811	EUROLIGHT E36, 3,5 V Ophthal-moskop mit Ladestecker 240V	EUROLIGHT E36, 3.5V ophthal-moscope with charg.plug 240V
01.28561.021	PICCOLIGHT E56, 2,5V Ophthal-moskop, night, Grünfilter, LED	PICCOLIGHT E56, 2.5V Ophtha-moscope,night,greenfilter,LED
01.28561.231	PICCOLIGHT E56, 2,5V Ophthal-moskop, sky, Grünfilter, LED	PICCOLIGHT E56, 2.5V Ophtha-moscope, sky,green filter,LED
01.28561.261	PICCOLIGHT E56, 2,5V Ophthal-moskop, stone, Grünfilter, LED	PICCOLIGHT E56,2.5V Ophthamo-scope, stone,green filter,LED
01.85255.021	EUROLIGHT E25, HL, Ophthal-moskop Kopf, allein, schwarz,	EUROLIGHT E25, HL,Ophthal-moscope head, only,black,
01.87561.021	Piccolight E56, HL,EU Ophthal-moskop Kopf, allein, night,	Piccolight E56, HL,EU Ophthal-moscope head, only,night,
01.87566.021	Piccolight E56, HL,US Ophthal-moskop Kopf, allein, night,	Piccolight E56, HL,US Ophthal-moscope head, only,night,
02.01008.002	BASIC-SET COMBILIGHT C10/E15 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E15 ophthalmoscope and otoscope
02.01104.002	BASIC-SET COMBILIGHT C10/E16 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E16 ophthalmoscope and otoscope
02.11001.002	BASIC-SET COMBILIGHT C10/E10 Ophthalmoskop und Otoskop	BASIC-SET COMBILIGHT C10/E10 ophthalmoscope and otoscope
02.11002.001	EUROLIGHT C10/E10 SET Ophthalmoskop und Otoskop	EUROLIGHTC10/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	EUROLIGHTF.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 otoscope 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), (LiIon)	Rechargeable battery, medium Lithium-Ion, 3.5 V (C),(LiIon)

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**DERMATOSKOP** Dermatoscopes
Zweckbestimmung / Intended use:	Diagnostikinstrument für die optische Untersuchung (nichtinvasiv) der oberflächlichen Hautstrukturen. Diagnostic instrument for optical examination (non-invasive) of superficial skin structures.

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: 4030155KaWe0103YV

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
DERMATOSKOP

List of devices accompanying the declaration of conformity
Dermatoscopes

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
01.31130.001	EUROLIGHT D30 Dermatoskop, 2,5 V in Tasche	EUROLIGHT D30 dermatoscope, 2,5 V in bag
01.31630.811	EUROLIGHT D30 LED standard Dermatoskop mit Ladestecker	EUROLIGHT D30 LED standard dermatoscope with charging
01.33100.021	PICCOLIGHT D, Dermatoskop 2,5 V, night in Stofftasche	PICCOLIGHT D, Dermatoscope 2,5 V, night in cloth bag
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), (LiIon)	Rechargeable battery, medium Lithium-Ion, 3.5 V (C),(LiIon)

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Otoskop/Ophthalmoskop-Wandstation** Wall mounted diagnostic set
Zweckbestimmung / Intended use:	Wandstation zur Spannungsversorgung für KaWe Otoskopköpfe & Ophthalmoskopköpfe mit 3,5 V Lampen. Wall station for power supply for KaWe otoscope heads & ophthalmoscope heads with 3.5 V lamps.

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: 4030155KaWe02SL

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

Asperg, 2021-04-29

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
Otoskop/Ophthalmoskop-Wandstation

List of devices accompanying the declaration of conformity
Wall mounted diagnostic set

Artikel-Nr. / Ref	Bezeichnung	Denomination
02.81000.002	MedCenter 5000 Wandstation, Grundmodul, 1 Griff	MedCenter 5000 wall mounted Set, basic module, 1 handle
02.81001.002	MedCenter 5000 Wandstation, Grund-/+ Ausbaumodul	MedCenter 5000 wall mounted Set,basic-/+ up-grading module
02.84000.002	MedCenter 5000 Wandstation, Ausbaumodul	MedCenter 5000 wall mounted set, upgrad. module
02.84001.002	MedCenter 5000 Wandstation, Ohrtrichtermodul	MedCenter 5000 wall mounted set, ear funnels module
02.85010.002	MedCenter 5000 Wandstation Set C/E56	MedCenter 5000 wall mounted Set C/E56
02.85020.002	MedCenter 5000 Wandstation Set F.O./E56, US	MedCenter 5000 wall mounted Set F.O./E56, US
02.85021.002	MedCenter 5000 Wandstation Set F.O./E56, EU	MedCenter 5000 wall mounted Set F.O./E56, EU
02.85030.002	MedCenter 5000 Wandstation Set F.O./E25	MedCenter 5000 wall mounted Set F.O./E25

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Laryngoskop, starr** Laryngoscopes, rigid
Zweckbestimmung / Intended use:	Für die direkte Einsichtnahme bzw. Inspektion des Kehlkopfes (Larynx) bei der Intubation. For direct viewing or inspection of the larynx during intubation.

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: 4030155KaWe03SN

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

Laryngoskop, starr

List of devices accompanying the declaration of conformity

Laryngoscopes, rigid

Artikel-Nr. / Ref	Bezeichnung	Denomination
03.11000.711	WL-Batterie-/Ladegriff, klein, 2,5 V	WL battery-/recharging handle, small, 2.5 V
03.11000.721	WL-Batterie-/Ladegriff, mittel, 2,5 V	WL battery-/recharging handle, medium, 2.5 V
03.11000.731	WL-Batteriegriff, groß, 2,5 V	WL battery handle, large, 2.5V
03.11001.721	WL-Economy-Batteriegriff blau, mittel, 2,5 V	WL Economy battery handle blue medium, 2.5 V
03.11002.721	WL Einmal-Batteriegriff Kunststoff, mittel, 2,5 V,	WL Single-use battery handle, plastic, medium, 2.5 V
03.12010.602	WL-Macintosh Spatel, Gr. 0	WL Macintosh blade,no. 0
03.12010.612	WL-Macintosh Spatel, Gr. 1	WL Macintosh blade,no. 1
03.12010.622	WL-Macintosh Spatel, Gr. 2	WL Macintosh blade,no. 2
03.12010.632	WL-Macintosh Spatel, Gr. 3	WL Macintosh blade,no. 3
03.12010.642	WL-Macintosh Spatel, Gr. 4	WL Macintosh blade,no. 4
03.12010.652	WL-Macintosh Spatel Gr. 5	WL Macintosh blade,no. 5
03.12011.602	WL-Economy Macintosh Spatel, Gr. 0, Sockel blau	WL Economy Macintosh blade, no. 0, socle blue
03.12011.612	WL-Economy Macintosh Spatel, Gr. 1, Sockel blau	WL Economy Macintosh blade, no. 1, socle blue
03.12011.622	WL-Economy Macintosh Spatel, Gr. 2, Sockel blau	WL Economy Macintosh blade, no. 2, socle blue
03.12011.632	WL-Economy Macintosh Spatel, Gr. 3, Sockel blau	WL Economy Macintosh blade, no. 3, socle blue
03.12011.642	WL-Economy Macintosh Spatel, Gr. 4, Sockel blau	WL Economy Macintosh blade, no. 4, socle blue

03.12011.652	WL-Economy Macintosh Spatel, Gr. 5, Sockel blau	WL Economy Macintosh blade, no. 5, socle blue
03.12020.592	WL-Miller Spatel, Gr. 00	WL Millerblade, no. 00
03.12020.602	WL-Miller Spatel, Gr. 0	WL Millerblade, no. 0
03.12020.612	WL-Miller Spatel, Gr. 1	WL Millerblade, no. 1
03.12020.622	WL-Miller Spatel, Gr. 2	WL Millerblade, no. 2
03.12020.632	WL-Miller Spatel, Gr. 3	WL Millerblade, no. 3
03.12020.642	WL-Miller Spatel, Gr. 4	WL Millerblade, no. 4
03.12021.592	WL-Economy Miller Spatel, Gr. 00, Sockel blau	WL Economy Miller blade, no. 00, socle blue
03.12021.602	WL-Economy Miller Spatel, Gr. 0, Sockel blau	WL Economy Miller blade, no. 0, socle blue
03.12021.612	WL-Economy Miller Spatel, Gr. 1, Sockel blau	WL Economy Miller blade, no. 1, socle blue
03.12021.622	WL-Economy Miller Spatel, Gr. 2, Sockel blau	WL Economy Miller blade, no. 2, socle blue
03.12021.632	WL-Economy Miller Spatel, Gr. 3, Sockel blau	WL Economy Miller blade, no. 3, socle blue
03.12021.642	WL-Economy Miller Spatel, Gr. 4, Sockel blau	WL Economy Miller blade, no. 4, socle blue
03.12030.602	WL-Foregger Spatel, Gr. 0	WL Foregger blade, no. 0
03.12030.612	WL-Foregger Spatel, Gr. 1	WL Foregger blade, no. 1
03.12030.622	WL-Foregger Spatel, Gr. 2	WL Foregger blade no. 2
03.12030.632	WL-Foregger Spatel, Gr. 3	WL Foregger blade, no. 3
03.12030.642	WL-Foregger Spatel, Gr. 4	WL Foregger blade, no. 4
03.12050.622	WL-FLAPLIGHT Macintosh Spatel, Gr. 2	WL FLAPLIGHT Macintosh blade, no. 2

03.12050.632	WL-FLAPLIGHT Macintosh Spatel, Gr. 3	WL FLAPLIGHT Macintosh blade, no. 3
03.12050.642	WL-FLAPLIGHT Macintosh Spatel, Gr. 4	WL FLAPLIGHT Macintosh blade, no. 4
03.12060.632	WL Polio Macintosh Spatel, Gr. 3	WL Polio Macintosh blade, no. 3
03.12060.642	WL Polio Macintosh Spatel, Gr. 4	WL Polio Macintosh blade, no. 4
03.14010.602	WL-LED Einmal Macintosh Spatel Metall, Gr. 0, unsteril	WL LED disposable Macintosh blade metal no. 0, non sterile
03.14010.612	WL-LED Einmal Macintosh Spatel Metall, Gr. 1, unsteril	WL LED disposable Macintosh blade metal no. 1, non sterile
03.14010.622	WL-LED Einmal Macintosh Spatel Metall, Gr. 2, unsteril	WL LED disposable Macintosh blade metal no. 2, non sterile
03.14010.632	WL-LED Einmal Macintosh Spatel Metall, Gr. 3, unsteril	WL LED disposable Macintosh blade metal no. 3, non sterile
03.14010.642	WL-LED Einmal Macintosh Spatel Metall, Gr. 4, unsteril	WL LED disposable Macintosh blade metal no. 4, non sterile
03.14020.592	WL-LED Einmal Miller Spatel Metall Gr. 00, unsteril	WL LED disposable Miller blade metal no.00, non sterile
03.14020.602	WL-LED Einmal Miller Spatel Metall, Gr. 0, unsteril	WL LED disposable Miller blade metal no. 0, non sterile
03.14020.612	WL-LED Einmal Miller Spatel Metall, Gr. 1, unsteril	WL LED disposable Miller blade metal no. 1, non sterile
03.14020.622	WL-LED Einmal Miller Spatel Metall, Gr. 2, unsteril	WL LED disposable Miller blade metal no. 2, non sterile
03.14020.632	WL-LED Einmal Miller Spatel Metall, Gr. 3, unsteril	WL LED disposable Miller blade metal no. 3, non sterile
03.14020.642	WL-LED Einmal Miller Spatel Metall, Gr. 4, unsteril	WL LED disposable Miller blade metal no. 4, non sterile
03.41000.721	F.O.-Batterie-/Ladegriff, mittel, 2,5 V	F.O. battery-/charging handle, medium, 2.5 V
03.41000.731	F.O.-Batteriegriff, groß, 2,5 V	F.O. battery handle, large, 2.5 V
03.41000.741	F.O.-Batteriegriff, kurz, 2,5 V	F.O. battery handle, short, 2.5 V
03.41000.811	F.O.-Ladegriff, mittel mit Ladestecker 240V	F.O. recharging handle, medium with charging plug 240V

03.41001.721	F.O.-Economy-Batteriegriff grün, mittel, 2,5 V	F.O. Economy battery handle green, medium, 2.5 V
03.41005.711	F.O.-Batterie-/Ladegriff, klein, 2,5 V	F.O. battery-/charging handle, small, 2.5 V
03.41010.521	F.O.-Ladegriff, mittel, inkl. Li-Ion Akku, 3,5 V	F.O. charging handle, medium, incl. Li-Ion accu, 3.5 V
03.41015.711	F.O.-Lagegriff, klein, inkl. NiMH Akku, 3,5 V	F.O. charging handle, small incl. NiMH accu, 3.5 V
03.41020.711	F.O. LED-Batteriegriff, klein, mit Standard-LED, 2,5 V	F.O. LED battery handle, small with standard LED, 2.5 V
03.41020.721	F.O. LED-Batteriegriff, mittel mit Standard-LED, 2,5 V	F.O. LED battery handle,medium with standard LED, 2.5 V
03.41020.741	F.O-LED Batteriegriff, kurz, 2,5 V, mit Standard LED	F.O. LED battery handle,short, 2.5 V, with standard LED
03.41022.721	F.O. LED Einmal-Batteriegriff Kunststoff, mittel, 2,5 V,	F.O. LED Single-usebattery handle, plastic, medium, 2.5 V
03.41030.711	F.O. LED-Batteriegriff, klein, mit high power LED, 2,5 V	F.O. LED battery handle, small with highpower LED, 2.5 V
03.41030.721	F.O. LED-Batteriegriff, mittel mit high power LED, 2,5 V	F.O. LED battery handle,medium with highpower LED, 2.5 V
03.41030.741	F.O-LED Batteriegriff, kurz, 2,5 V, mit high power LED	F.O. LED battery handle,short, 2.5 V, with high power LED
03.41100.721	F.O.-Batterie-/Ladegriff, mittel, inkl. NiMH Akku 2,5 V	F.O. battery-/charging handle, medium, incl. NiMH accu, 2.5 V
03.41105.711	F.O.-Batterie-/Ladegriff, klein, inkl. NiMH Akku, 2,5 V	F.O. battery-/charging handle, small, incl. NiMH accu, 2.5 V
03.41140.521	F.O.-LED Ladegriff, mittel, inkl. Li-Ion Akku	F.O. LED charging handle, medium, inkl. Li-Ion Accu
03.41145.711	F.O.-LED Ladegriff, klein, inkl. NiMH Akku, 3,5V	F.O. LED charging handle, small, incl. NiMH Accu, 3.5 V
03.42011.601	F.O.-Economy Macintosh Spatel, Gr. 0, Sockel grün	F.O. Economy Macintosh blade, no. 0, socle green
03.42011.611	F.O.-Economy Macintosh Spatel, Gr. 1, Sockel grün	F.O. Economy Macintosh blade, no. 1, socle green
03.42011.621	F.O.-Economy Macintosh Spatel, Gr. 2, Sockel grün	F.O. Economy Macintosh blade, no. 2, socle green
03.42011.631	F.O.-Economy Macintosh Spatel, Gr. 3, Sockel grün	F.O. Economy Macintosh blade, no. 3, socle green

03.42011.641	F.O.-Economy Macintosh Spatel, Gr. 4, Sockel grün	F.O. Economy Macintosh blade, no. 4, socle green
03.42011.651	F.O.-Economy Macintosh Spatel, Gr. 5, Sockel grün	F.O. Economy Macintosh blade, no. 5, socle green
03.42013.601	F.O.-Macintosh Spatel, Gr. 0	F.O. Macintosh blade, no. 0
03.42013.611	F.O.-Macintosh Spatel, Gr. 1	F.O. Macintosh blade, no. 1
03.42013.621	F.O.-Macintosh Spatel, Gr. 2	F.O. Macintosh blade, no. 2
03.42013.631	F.O.-Macintosh Spatel, Gr. 3	F.O. Macintosh blade, no. 3
03.42013.641	F.O.-Macintosh Spatel, Gr. 4	F.O. Macintosh blade, no. 4
03.42013.651	F.O.-Macintosh Spatel, Gr. 5	F.O. Macintosh blade, no. 5
03.42021.591	F.O.-Economy Miller Spatel, Gr. 00, Sockel grün	F.O. Economy Millerblade, no 00, socle green
03.42021.601	F.O.-Economy Miller Spatel, Gr. 0, Sockel grün	F.O. Economy Millerblade, no 0, socle green
03.42021.611	F.O.-Economy Miller Spatel, Gr. 1, Sockel grün	F.O. Economy Millerblade, no. 1, socle green
03.42021.621	F.O.-Economy Miller Spatel, Gr. 2, Sockel grün	F.O. Economy Millerblade, no. 2, socle green
03.42021.631	F.O.-Economy Miller Spatel, Gr. 3, Sockel grün	F.O. Economy Millerblade, no. 3, socle green
03.42021.641	F.O.-Economy Miller Spatel, Gr. 4, Sockel grün	F.O. Economy Millerblade, no. 4, socle green
03.42023.591	F.O.-Miller Spatel, Gr. 00	F.O. Miller blade, no. 00
03.42023.601	F.O.-Miller Spatel, Gr. 0	F.O. Miller blade, no. 0
03.42023.611	F.O.-Miller Spatel, Gr. 1	F.O. Miller blade, no. 1
03.42023.621	F.O.-Miller Spatel, Gr. 2	F.O. Miller blade, no. 2
03.42023.631	F.O.-Miller Spatel, Gr. 3	F.O. Miller blade, no. 3

03.42023.641	F.O.-Miller Spatel, Gr. 4	F.O. Miller blade, no. 4
03.42033.601	F.O.-Foregger Spatel, Gr. 0	F.O. Foregger blade, no. 0
03.42033.611	F.O.-Foregger Spatel, Gr. 1	F.O. Foregger blade, no. 1
03.42033.621	F.O.-Foregger Spatel, Gr. 2	F.O. Foregger blade, no. 2
03.42033.631	F.O.-Foregger Spatel, Gr. 3	F.O. Foregger blade, no. 3
03.42033.641	F.O.-Foregger Spatel, Gr. 4	F.O. Foregger blade, no. 4
03.42053.621	F.O. FLAPLIGHT Macintosh Spatel, Gr. 2	F.O.-FLAPLIGHT Macintosh blade, no. 2
03.42053.631	F.O. FLAPLIGHT Macintosh Spatel, Gr. 3	F.O.-FLAPLIGHT Macintosh blade, no. 3
03.42053.641	F.O. FLAPLIGHT Macintosh Spatel, Gr. 4	F.O.-FLAPLIGHT Macintosh blade, no. 4
03.42063.631	F.O.-Polio Macintosh Spatel, Gr. 3	F.O. Polio Macintosh blade, no. 3
03.42063.641	F.O.-Polio Macintosh Spatel, Gr. 4	F.O. Polio Macintosh blade, no. 4
03.42073.621	F.O.-Tepro Macintosh Spatel, Gr. 2	F.O. Tepro Macintosh blade, no. 2
03.42073.631	F.O.-Tepro Macintosh Spatel, Gr. 3	F.O. Tepro Macintosh blade, no. 3
03.42073.641	F.O.-Tepro Macintosh Spatel, Gr. 4	F.O. Tepro Macintosh blade, no. 4
03.42244.601	F.O.-MEGALIGHT Macintosh Spatel, Gr. 0	F.O. MEGALIGHT Macintosh blade, no. 0
03.42244.611	F.O.-MEGALIGHT Macintosh Spatel, Gr. 1	F.O. MEGALIGHT Macintosh blade, no. 1
03.42244.621	F.O.-MEGALIGHT Macintosh Spatel, Gr. 2	F.O. MEGALIGHT Macintosh blade, no. 2
03.42244.631	F.O.-MEGALIGHT Macintosh Spatel, Gr. 3	F.O. MEGALIGHT Macintosh blade, no. 3
03.42244.641	F.O.-MEGALIGHT Macintosh Spatel, Gr. 4	F.O. MEGALIGHT Macintosh blade, no. 4

03.42244.651	F.O.-MEGALIGHT Macintosh Spatel, Gr. 5	F.O. MEGALIGHT Macintosh blade, no. 5
03.42246.591	F.O.-MEGALIGHT Miller Spatel, Gr. 00	F.O. MEGALIGHT Miller blade, no. 00
03.42246.601	F.O.-MEGALIGHT Miller Spatel, Gr. 0	F.O. MEGALIGHT Miller blade, no. 0
03.42246.611	F.O.-MEGALIGHT Miller Spatel, Gr. 1	F.O. MEGALIGHT Miller blade, no. 1
03.42246.621	F.O.-MEGALIGHT Miller Spatel, Gr. 2	F.O. MEGALIGHT Miller blade, no. 2
03.42246.631	F.O.-MEGALIGHT Miller Spatel, Gr. 3	F.O. MEGALIGHT Miller blade, no. 3
03.42246.641	F.O.-MEGALIGHT Miller Spatel, Gr. 4	F.O. MEGALIGHT Miller blade, no. 4
03.42254.621	F.O. FLAPLIGHT MEGALIGHT Macintosh Spatel, Gr. 2	F.O.-FLAPLIGHT MEGALIGHT Macintoshblade, no. 2
03.42254.631	F.O. FLAPLIGHT MEGALIGHT Macintosh Spatel, Gr. 3	F.O.-FLAPLIGHT MEGALIGHT Macintoshblade, no. 3
03.42254.641	F.O. FLAPLIGHT MEGALIGHT Macintosh Spatel, Gr. 4	F.O.-FLAPLIGHT MEGALIGHT Macintoshblade, no. 4
03.43014.622	Einmal Macintosh Spatel Kunststoff, Gr. 2, unsteril	Disposable Macintosh blade plastic, no. 2, non sterile
03.43014.632	Einmal Macintosh Spatel Kunststoff, Gr. 3, unsteril	Disposable Macintosh blade plastic, no. 3, non sterile
03.43014.642	Einmal Macintosh Spatel Kunststoff, Gr. 4, unsteril	Disposable Macintosh blade plastic, no. 4, non sterile
03.43024.602	Einmal Miller Spatel Kunststoff, Gr. 0, unsteril	Disposable Miller blade plastic, no. 0, non sterile
03.43024.612	Einmal Miller Spatel Kunststoff, Gr. 1, unsteril	Disposable Miller blade plastic, no. 1, non sterile
03.43024.622	Einmal Miller Spatel Kunststoff, Gr. 2, unsteril	Disposable Miller blade plastic, no. 2, non sterile
03.43024.632	Einmal Miller Spatel Kunststoff, Gr. 3, unsteril	Disposable Miller blade plastic, no. 3, non sterile
03.44014.602	Einmal Macintosh Spatel Metall, Gr. 0, unsteril	Disposable Macintosh blade metal, no. 0, non sterile
03.44014.612	Einmal Macintosh Spatel Metall, Gr. 1, unsteril	Disposable Macintosh blade metal, no. 1, non sterile

03.44014.622	Einmal Macintosh Spatel Metall, Gr. 2, unsteril	Disposable Macintosh blade metal, no. 2, non sterile
03.44014.632	Einmal Macintosh Spatel Metall, Gr. 3, unsteril	Disposable Macintosh blade metal, no. 3, non sterile
03.44014.642	Einmal Macintosh Spatel Metall, Gr. 4, unsteril	Disposable Macintosh blade metal, no. 4, non sterile
03.44024.592	Einmal Miller Spatel Metall, Gr. 00, unsteril	Disposable Miller blade metal, no. 00, non sterile
03.44024.602	Einmal Miller Spatel Metall, Gr. 0, unsteril	Disposable Miller blade metal, no. 0, non sterile
03.44024.612	Einmal Miller Spatel Metall, Gr. 1, unsteril	Disposable Miller blade metal, no. 1, non sterile
03.44024.622	Einmal Miller Spatel Metall, Gr. 2, unsteril	Disposable Miller blade metal, no. 2, non sterile
03.44024.632	Einmal Miller Spatel Metall, Gr. 3, unsteril	Disposable Miller blade metal, no. 3, non sterile
03.44024.642	Einmal Miller Spatel Metall, Gr. 4, unsteril	Disposable Miller blade metal, no. 4, non sterile
03.51020.011	WL-Laryngoskop-Set für Erwachsene	WL-Laryngoscope-Set for adults
03.51022.002	Economy Laryngoskop-Set C für Erwachsene	Economy Laryngoscope Set C for adults
03.51120.011	WL-Laryngoskop-Set für Neonatal	WL-Laryngoscope Set for Neonatal
03.51720.011	WL-Laryngoskop-Set für die Pädiatrie	WL-Laryngoscope Set for paediatrics
03.51790.011	WL-Laryngoskop-Set für Erw./ Pädiatrie	WL-Laryngoscope Set for adults /paediatrics
03.62020.011	F.O. Laryngoskop-Set 2,5 V für Erwachsene	F.O. Laryngoscope Set 2.5 V for adults
03.62022.002	Economy Laryngoskop-Set F.O. für Erwachsene	Economy Laryngoscope Set F.O. for adults
03.62125.011	F.O. Laryngoskop-Set 2,5 V für Neonatal	F.O. Laryngoscope Set 2.5 V for Neonatal
03.62320.011	F.O. Laryngoskop-Set 2,5 V für Erwachsene	F.O. Laryngoscope Set 2.5 V for adults
03.62720.011	F.O. Laryngoskop-Set 2,5 V für die Pädiatrie	F.O. Laryngoscope Set 2.5 V for paediatrics

03.62790.011	F.O. Laryngoskop-Set 2,5 V für Erw./Pädiatrie	F.O. Laryngoscope Set 2.5 V for adults/paediatrics
03.63020.722	F.O. Laryngoskop-Set 3,5 V für Erwachsene, Macintosh	F.O. Laryngoscope Set 3.5 V for adults, Macintosh
03.63320.722	F.O. Laryngoskop-Set 3,5 V für Erwachsene, MEGALIGHT Macintosh	F.O. Laryngoscope Set 3.5 V for adults, MEGALIGHT Macintosh
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), (LiIon)	Rechargeable battery, medium Lithium-Ion, 3.5 V (C),(LiIon)
S-03.62083.013	F.O. Laryngoskop Set 2,5V für Erwachsene/ Pädiatrie, Economy Macintosh	F.O. Laryngoscope Set 2,5 V for adults/ pediatrics, Economy Macintosh
S-03.62103.013	F.O. Laryngoskop Set 2,5V für Erwachsene/ Pädiatrie, Economy Miller	F.O. Laryngoscope Set 2,5 V for adults/ pediatrics, Economy Miller
S-03.62703.013	F.O. Laryngoskop Set 2,5V für Erwachsene/ Pädiatrie, Economy Macintosh/ Miller	F.O. Laryngoscope Set 2,5 V for adults/ pediatrics, Economy Macintosh/ Miller

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Hiermit erklären wir / We hereby declare
KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstrasse 56
71679 Asperg
Deutschland / Germany

in alleiniger Verantwortung, dass die nachfolgend genannte Produktfamilie mit den aufgelisteten Produkten, den grundlegenden Anforderungen des Anhang I der Richtlinie 93/42/EWG über Medizinprodukte unter Berücksichtigung der Änderungsrichtlinie 2007/47/EG entsprechen.

Das Konformitätsbewertungsverfahren wurde nach Anhang VII in Verbindung mit Anhang V der Richtlinie 93/42/EWG durchgeführt.

Produktname: **Blutdruckmessgerät, aneroid**
Die Medizinprodukte werden nach Richtlinie 93/42/EWG Anhang IX der Klasse Im zugeordnet.

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in sole responsibility that the following product family with listed products, are in compliance with the relevant provisions of Annex I of the directive 93/42/EEC concerning medical devices in consideration of change directive 2007/47/EC.

The conformity assessment procedure has been carried out in accordance with Annex VII in conjunction with Annex V of the directive 93/42/EEC.

Name of product: **Aneroid blood pressure measuring devices**
The medical devices are allocated in accordance with the directive 93/42/EEC Annex IX to Class Im.

Die im Folgenden benannte Stelle ist am Konformitätsbewertungsverfahren beteiligt:
Involved in the conformity assessment procedure is the below-mentioned notified body:

Benannte Stelle / Notified Body: SIQ Ljubljana

Kennnummer / Notified body number: 1304

CE 1304

Diese Erklärung ist gültig bis 10. Januar 2024.
This declaration is valid until 10th January 2024.

Asperg, 2021-02-16

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte

Blutdruckmessgerät, aneroid

List of devices accompanying the declaration of conformity

Aneroid blood pressure measuring devices

Artikel-Nr. / Ref	Bezeichnung	Denomination
04.11134.232	MASTERMED A1	MASTERMED A1
04.11144.232	MASTERMED A1+	MASTERMED A1+
04.12134.232	MASTERMED A2	MASTERMED A2
04.12144.232	MASTERMED A2+	MASTERMED A2+
04.12334.232	MASTERMED A3	MASTERMED A3
04.32730.232	MASTERMED C, Tischmodell	MASTERMED C, table model
04.32740.232	MASTERMED C, Stativmodell	MASTERMED C, mobile stand model
04.32750.232	MASTERMED C, Wandmodell	MASTERMED C, wall model

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Hiermit erklären wir / We hereby declare
KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstrasse 56
71679 Asperg
Deutschland / Germany

in alleiniger Verantwortung, dass die nachfolgend genannte Produktfamilie mit den aufgelisteten Produkten, den grundlegenden Anforderungen des Anhang I der Richtlinie 93/42/EWG über Medizinprodukte unter Berücksichtigung der Änderungsrichtlinie 2007/47/EG entsprechen.

Das Konformitätsbewertungsverfahren wurde nach Anhang VII in Verbindung mit Anhang V der Richtlinie 93/42/EWG durchgeführt.

Produktname: **Ein-Patienten-Manschette**
Die Medizinprodukte werden nach Richtlinie 93/42/EWG Anhang IX der Klasse Im zugeordnet.

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in sole responsibility that the following product family with listed products, are in compliance with the relevant provisions of Annex I of the directive 93/42/EEC concerning medical devices in consideration of change directive 2007/47/EC.

The conformity assessment procedure has been carried out in accordance with Annex VII in conjunction with Annex V of the directive 93/42/EEC.

Name of product: **Single-patient-cuff**
The medical devices are allocated in accordance with the directive 93/42/EEC Annex IX to Class Im.

Die im Folgenden benannte Stelle ist am Konformitätsbewertungsverfahren beteiligt:
Involved in the conformity assessment procedure is the below-mentioned notified body:

Benannte Stelle / Notified Body: SIQ Ljubljana

Kennnummer / Notified body number: 1304

CE 1304

Diese Erklärung ist gültig bis 10. Januar 2024.
This declaration is valid until 10th January 2024.

Asperg, 2021-04-23

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
Ein-Patienten-Manschette

List of devices accompanying the declaration of conformity
Single-patient-cuff

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
04.85140.221	Ein-Patienten-Manschette Kind	Single-patient-cuff child
04.85140.231	Ein-Patienten-Manschette Erwachsener	Single-patient-cuff adult
04.85140.241	Ein-Patienten-Manschette Übergröße	Single-patient-cuff large adult

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Hiermit erklären wir / We hereby declare
KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstrasse 56
71679 Asperg
Deutschland / Germany

in alleiniger Verantwortung, dass die nachfolgend genannte Produktfamilie mit den aufgelisteten Produkten, den grundlegenden Anforderungen des Anhang I der Richtlinie 93/42/EWG über Medizinprodukte unter Berücksichtigung der Änderungsrichtlinie 2007/47/EG entsprechen.

Das Konformitätsbewertungsverfahren wurde nach Anhang VII in Verbindung mit Anhang V der Richtlinie 93/42/EWG durchgeführt.

Produktname: **Manschette-Blutdruck**
Die Medizinprodukte werden nach Richtlinie 93/42/EWG Anhang IX der Klasse Im zugeordnet.

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in sole responsibility that the following product family with listed products, are in compliance with the relevant provisions of Annex I of the directive 93/42/EEC concerning medical devices in consideration of change directive 2007/47/EC.

The conformity assessment procedure has been carried out in accordance with Annex VII in conjunction with Annex V of the directive 93/42/EEC.

Name of product: **Cuff**
The medical devices are allocated in accordance with the directive 93/42/EEC Annex IX to Class Im.

Die im Folgenden benannte Stelle ist am Konformitätsbewertungsverfahren beteiligt:
Involved in the conformity assessment procedure is the below-mentioned notified body:

Benannte Stelle / Notified Body: SIQ Ljubljana

Kennnummer / Notified body number: 1304

CE 1304

Diese Erklärung ist gültig bis 10. Januar 2024.
This declaration is valid until 10th January 2024.

Asperg, 2021-04-23

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
Manschette-Blutdruck

List of devices accompanying the declaration of conformity
Cuff

Artikel-Nr. / Ref	Bezeichnung	Denomination
04.85104.211	Manschette A1, A1+, schwarz, 1 Schlauch Kleinkind	Cuff A1, A1+, black, 1 tube infant
04.85104.221	Manschette A1, A1+, schwarz, 1 Schlauch Kind	Cuff A1, A1+, black, 1 tube child
04.85104.231	Manschette A1, A1+, schwarz, 1 Schlauch Erwachsener	Cuff A1, A1+, black, 1 tube adult
04.85104.241	Manschette A1, A1+, schwarz, 1 Schlauch Übergröße	Cuff A1, A1+, black, 1 tube large adult
04.85204.211	Manschette A2, A2+, schwarz, 2 Schlauch Kleinkind	Cuff A2, A2+, black, 2 tubes infant
04.85204.221	Manschette A2, A2+, schwarz, 2 Schlauch Kind	Cuff A2, A2+, black, 2 tubes child
04.85204.231	Manschette A2, A2+, schwarz, 2 Schlauch Erwachsener	Cuff A2, A2+, black, 2 tubes adult
04.85204.241	Manschette A2, A2+, schwarz, 2 Schlauch Übergröße	Cuff A2, A2+, black, 2 tubes large adult
04.86600.221	Manschette A3, schwarz, 2 Schlauch Kind	Cuff A3, black, 2 tubes child
04.86600.231	Manschette A3, schwarz, 2 Schlauch Erwachsener	Cuff A3, black, 2 tubes adult
04.86600.241	Manschette A3, schwarz, 2 Schlauch Übergröße	Cuff A3, black, 2 tubes large adult

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

Hiermit erklären wir / We hereby declare
KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstrasse 56
71679 Asperg
Deutschland / Germany

in alleiniger Verantwortung, dass die nachfolgend genannte Produktfamilie mit den aufgelisteten Produkten, den grundlegenden Anforderungen des Anhang I der Richtlinie 93/42/EWG über Medizinprodukte unter Berücksichtigung der Änderungsrichtlinie 2007/47/EG entsprechen.
Die Vorschriften der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten werden erfüllt.
Das Konformitätsbewertungsverfahren wurde nach Anhang VII in Verbindung mit Anhang V der Richtlinie 93/42/EWG durchgeführt.

Produktname: **IONTOPHORESEGERÄT**
Die Medizinprodukte werden nach Richtlinie 93/42/EWG Anhang IX der Klasse IIa zugeordnet.

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in sole responsibility that the following product family with listed products, are in compliance with the relevant provisions of Annex I of the directive 93/42/EEC concerning medical devices in consideration of change directive 2007/47/EC.
They comply with the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
The conformity assessment procedure has been carried out in accordance with Annex VII in conjunction with Annex V of the directive 93/42/EEC.

Name of product: **Iontophoresis units**
The medical devices are allocated in accordance with the directive 93/42/EEC Annex IX to Class IIa.

Die im Folgenden benannte Stelle ist am Konformitätsbewertungsverfahren beteiligt:
Involved in the conformity assessment procedure is the below-mentioned notified body:

Benannte Stelle / Notified Body: SIQ Ljubljana
Kennnummer / Notified body number: 1304

CE 1304

Diese Erklärung ist gültig bis 10. Januar 2024.
This declaration is valid until 10th January 2024.

Asperg, 2021-02-16

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
IONTOPHORESEGERÄT

List of devices accompanying the declaration of conformity
Iontophoresis units

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
05.11110.002	SwiSto3 Iontophoresegerät-Set mit Ladestecker	SwiSto3 iontophoresis device, set with charg. plug
05.19020.021	Behandlungswanne schwarz für Iontophoresegerät	Tub black for Iontophoresis device
05.19030.021	Verbindungskabel, allein, schwarz, VE = 2 Stück	Connection cable, only black, PU = 2 pcs.
05.19040.021	Elektroden Platten, Kabel schwarz VPE 2Stk.	Electrodeplates, cable black
05.19050.003	Schaumstoffauflagen VE = 2 St.	Foam pads PU = 2 pcs.
05.19080.001	Flächenelektroden, Edel- stahl mit Schwammtaschen,	Surface electrodes stainless steel with sponge pocket
05.19090.001	Ersatzschwammtaschen, allein für Flächenelektroden VPE 2 St.	Spare sponge pockets, only for surface electrodes
05.19110.002	SwiSto3 Iontophoresegerät allein, jedoch mit Ladestecker	SwiSto3 iontophoresis device only, however with charg. plug
05.19170.002	Ladestecker 10,5 V, allein für SwiSto3 EU-Version	Charging plug 10.5 V, only for SwiSto3 EU-version

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

Artikel-Nr. / Ref	Bezeichnung	Denomination
06.10100.014	Colorscop-Steth. "Plano" rot	Colorscop-plano stethoscope red
06.10100.024	Colorscop-Steth. "Plano" schwarz	Colorscop-plano stethoscope black
06.10100.034	Colorscop-Steth. "Plano" blau	Colorscop-plano stethoscope blue
06.10100.044	Colorscop-Steth. "Plano" grün	Colorscop-plano stethoscope green
06.10100.054	Colorscop-Steth. "Plano" gelb	Colorscop-plano stethoscope yellow
06.10100.094	Colorscop-Steth. "Plano" lila	Colorscop-plano stethoscope violet
06.10100.124	Colorscop-Steth."Plano" türkis	Colorscop-plano stethoscope turquoise
06.10100.134	Colorscop-Steth. "Plano" pink	Colorscop-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	Colorscop-Steth. "Duo" rot	Colorscop-duo stethoscope red
06.22100.024	Colorscop-Steth. "Duo" schwarz	Colorscop-duo stethoscope black
06.22100.034	Colorscop-Steth. "Duo" blau	Colorscop-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

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Perkussionshammer** Percussors
Zweckbestimmung / Intended use:	Diagnostikinstrument zur Perkussion (das ärztliche Abklopfen). Diagnostic instrument for percussion (the medical tapping).

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: 4030155KaWe07SW

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

Perkussionshammer

List of devices accompanying the declaration of conformity

Percussors

Artikel-Nr. / Ref	Bezeichnung	Denomination
07.05100.001	Reflex-Perkussions-Hammer n. Babinsky umschraubbar	Reflex and percussion hammer according to Babinsky
07.05300.001	Reflexhammer nach Babinsky mit elastischem Stiel	Reflex hammer according to Babinsky,with elastic shaft
07.10324.001	Reflexhammer nach Rossier 24 cm lang	Reflex hammer according to Rossier, length 24 cm
07.10336.001	Reflexhammer nach Rossier, 36 cm lang	Reflex hammer according to Rossier, lenght 36 cm
07.15204.021	Colorflex-Reflexhammer, groß schwarz	Reflex hammer Colorflex, large black
07.15204.031	Colorflex-Reflexhammer, groß blau	Reflex hammer Colorflex, large blue
07.15204.262	Colorflex-Reflexhammer, groß grau	Reflex hammer Colorflex, large grey
07.25130.001	Kombinationshammer Varioflex nach Fassbender	Combination hammer Varioflex according to Fassbender
07.35102.001	Reflexhammer nach Trömner, Original-Modell	Reflex hammer according to Troemner,original model
07.35201.001	Reflexhammer nach Trömner leicht	Reflex hammer according to Troemner, light
07.35222.001	Trömner-Reflexhammer mit schwarzem Kunststoffgriff	Reflex hammer according to Troemner with plastic shaft
07.35231.001	Reflexhammer nach Trömner, leicht, inkl. Nadel	Reflex hammer acc. to Troemner light, with needle
07.35232.001	Reflexhammer nach Trömner schwer	Reflex hammer according to Troemner, heavy
07.40232.001	Witroe-Reflexhammer mit Pinsel und Nadel	Witroe Reflex hammer with brush and needle
07.45130.001	Neurologischer Hammer nach Buck	Neurological hammer acc. to Buck
07.45230.001	Neurologischer Hammer nach Buck mit Kunststoff-Griff	Neurological hammer according to Buck with plastic shaft

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Stimmgabel** Tuning forks
Zweckbestimmung / Intended use:	Medizinische Stimmgabeln für z. B. Gehör- & Sensibilitätsprüfungen mittels Schallleitung. Medical tuning forks for e.g. hearing & sensitivity testing using sound conduction.

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: 4030155KaWe08SY

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
Stimmgabel

List of devices accompanying the declaration of conformity
Tuning forks

Artikel-Nr. / Ref	Bezeichnung	Denomination
08.11044.011	Stimmgabel mit Plastikfuß a1 440	Tuning fork with plastic stand a1 440
08.12012.111	Stimmgabel nach Rydel Seiffer mit Fuß c128/c64	Tuning fork according to Rydel Seiffer c128/c64
08.13012.011	Stimmgabel nach Lucae mit Plastikfuß c128	Tuning fork according to Lucae with plastic foot c128
08.13012.111	Stimmgabel mit Dämpfer und Plastikfuß c128	Tuning fork with silencer and plastic foot c128
08.13025.011	Stimmgabel nach Lucae mit Plastikfuß c1 256	Tuning fork according to Lucae with plastic foot c1 256
08.13051.011	Stimmgabel nach Lucae mit Plastikfuß c2 512	Tuning fork according to Lucae with plastic foot c2 512
08.13102.011	Stimmgabel nach Lucae mit Plastikfuß c3 1024	Tuning fork according to Lucae with plastic foot c3 1024
08.13204.011	Stimmgabel nach Lucae mit Plastikfuß c4 2048	Tuning fork according to Lucae with plastic foot c4 2048
08.13409.011	Stimmgabel nach Lucae mit Plastikfuß c5 4096	Tuning fork according to Lucae with plastic foot c5 4096
08.14012.101	Aluminium-Stimmgabel mit Dämpfer c 128	Aluminium tuning fork with dampers c128
08.14025.001	Aluminium-Stimmgabel ohne Dämpfer c1 256	Aluminium tuning fork without dampers c1 256
08.14025.101	Aluminium-Stimmgabel mit Dämpfer c1 256	Aluminium tuning fork with dampers c1 256
08.14051.001	Aluminium-Stimmgabel ohne Dämpfer c2 512	Aluminium tuning fork without dampers c2 512
08.14102.001	Aluminium-Stimmgabel ohne Dämpfer c3 1024	Aluminium tuning fork without dampers c3 1024
08.14204.001	Aluminium-Stimmgabel ohne Dämpfer c4 2048	Aluminium tuning fork without dampers c4 2048
08.15012.001	Stimmgabel ohne Dämpfer c128	Tuning fork without dampers c128

08.15012.101	Stimmgabel mit Dämpfer c128	Tuning fork with dampers c128
08.15025.001	Stimmgabel ohne Dämpfer c1 256	Tuning fork without dampers c1 256
08.15051.001	Stimmgabel ohne Dämpfer c2 512	Tuning fork without dampers c2 512
08.15102.001	Stimmgabel ohne Dämpfer c3 1024	Tuning fork without dampers c3 1024
08.15204.001	Stimmgabel ohne Dämpfer c4 2048	Tuning fork without dampers c4 2048
08.15409.001	Stimmgabel ohne Dämpfer c5 4096	Tuning fork without dampers c5 4096
08.24001.001	Stimmgabel-Set aus Aluminium 5 Stück	Tuning fork set made of aluminium, 5 pcs

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Infusionshalter** Intravenous hangers
Zweckbestimmung / Intended use:	Zur Verabreichung von Schwerkraftinfusionen (Infusionsflaschen/ –beutel) im klinischen Bereich und im Heimbereich (Pflege- & Altenheime etc.). For the administration of gravity infusions (infusion bottles/ bags) in the clinical area and in the home area (nursing homes, etc.).

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: 4030155KaWe090124

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
Infusionshalter

List of devices accompanying the declaration of conformity
Intravenous hangers

Artikel-Nr. / Ref	Bezeichnung	Denomination
09.11005.002	Infusionsständer, 5-Fuß Edelstahl	Infusion stand, 5-foot, stainlesssteel
09.11010.002	Infusionsständer, 5-Fuß Edelstahl, schwere Ausführung,	Infusion stand, stainless steel, 5-foot, heavy version
09.91012.001	Tropfglas, Teile Nr. 12, für alle KaWe Infusionsständer	Drop glass, no. 12 to all KaWe infusion stands
09.91016.001	Standard-Sicherheitshaken, Teile Nr. 16	Standard safety hook, no. 16 to infusion stand
09.91111.001	Kunststoffhalterung für Tropf-glas, Teile Nr. 11	Plastic mount for IV bottle, no. 11 to infusion stand
09.91210.021	Standard-Sicherheitshaken, Teile Nr. 10	Standard safety hook, no. 10 for all infusion stand

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Tisch, Untersuchung/Behandlung** Table, diagnostic/examination
Zweckbestimmung / Intended use:	Untersuchungs-, Ruhe- und Behandlungsliege zum Einsatz in medizinisch genutzten Räumen. Examination, resting and treatment couch for use in medically used rooms.

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: 4030155KaWe090226

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
Tisch, Untersuchung/Behandlung

List of devices accompanying the declaration of conformity
Table, diagnostic/examination

Artikel-Nr. / Ref	Bezeichnung	Denomination
09.49110.022	Untersuchungs-/Praxisliege, schwarz, neue Version	Examination couch, black, new version
09.49110.032	Untersuchungs-/Praxisliege, blau, neue Version	Examination couch, blue, new version
09.49110.062	Untersuchungs-/Praxisliege, grau, neue Version	Examination couch, grey, new version

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Leuchte, Untersuchung** Lights, examination
Zweckbestimmung / Intended use:	Untersuchungsleuchte zum beleuchten des Arbeitsfeldes/ Patienten mit einem schattenfreien, "kalten" Hochleistungslicht. Examination light for illuminating the work area/patient with a shadow-free, "cold" high-power light.

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: 4030155KaWe10SK

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
Leuchte, Untersuchung

List of devices accompanying the declaration of conformity
Lights, examination

Artikel-Nr. / Ref	Bezeichnung	Denomination
10.11010.002	MASTERLIGHT HL	MASTERLIGHT HL
10.11020.002	MASTERLIGHT LED	MASTERLIGHT LED
10.12010.002	MASTERLIGHT HL, ohne fahrbares Stativ	MASTERLIGHT HL, w / o mobile stand
10.12020.002	MASTERLIGHT LED, ohne fahrbares Stativ	MASTERLIGHT LED, w / o mobile stand
10.71011.002	MASTERLIGHT LED 1000	MASTERLIGHT LED 1000
10.71016.002	MASTERLIGHT LED 2000	MASTERLIGHT LED 2000
10.71021.002	MASTERLIGHT LED 3000	MASTERLIGHT LED 3000
10.71021.102	MASTERLIGHT LED 3000F	MASTERLIGHT LED 3000F
10.71030.002	MASTERLIGHT Untersuchungs- leuchte HL, 50W	MASTERLIGHT examination lamp HL, 50W
10.71031.002	MASTERLIGHT LED 4000	MASTERLIGHT LED 4000
10.71031.102	MASTERLIGHT LED 4000F	MASTERLIGHT LED 4000F

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Pinzette** Tweezer
Zweckbestimmung / Intended use:	Pinzette für die Anwendung an Mensch & Tier zur Entfernung von Zecken. Tweezers for use on humans & animals to remove ticks.

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: 4030155KaWe1102Z2

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

Pinzette

List of devices accompanying the declaration of conformity

Tweezer

Artikel-Nr. / Ref	Bezeichnung	Denomination
11.10001.002	Zecken-Fix, Pinzette	Tick-Fix, tweezers

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Schere, Verband** Scissors, bandage
Zweckbestimmung / Intended use:	Zum Schneiden von Verbandsstoffen und Durchtrennen von Kleidungsstücken. For cutting bandages and cutting through garments.

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: 4030155KaWe1103 Z4

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
Schere, Verband

List of devices accompanying the declaration of conformity
Scissors, bandage

Artikel-Nr. / Ref	Bezeichnung	Denomination
11.15010.011	Allzweck-Verband-Schere, groß rot	Universalscissors, large, red
11.15010.021	Allzweck-Verband-Schere, groß schwarz	Universalscissors, large, black
11.15010.031	Allzweck-Verband-Schere, groß blau	Universalscissors, large, blue
11.15010.051	Allzweck-Verband-Schere, groß gelb	Universalscissors, large, yellow

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Spekulum, vaginal** Specula, Vaginal
Zweckbestimmung / Intended use:	Medizinisches Instrument für die gynäkologische Untersuchung der Scheide und des Muttermunds. Medical instrument for gynecological examination of the vagina and cervix.

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: 4030155KaWe1104Z6

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
Spekulum, vaginal

List of devices accompanying the declaration of conformity
Specula, Vaginal

Artikel-Nr. / Ref	Bezeichnung	Denomination
11.40100.001	Scheidenspekulum Cusco für Jungfrauen, Edelstahl	Vaginal specula, Cusco-virgin model, stainless steel
11.40110.001	Scheidenspekulum Cusco Standard Gr. 1, Edelstahl	Vaginal specula,Cusco-standard no. 1, stainless steel
11.40120.001	Scheidenspekulum Cusco Standard Gr. 2, Edelstahl	Vaginal specula,Cusco-standard no. 2, stainless steel
11.40130.001	Scheidenspekulum Cusco Standard Gr. 3, Edelstahl	Vaginal specula,Cusco-standard no. 3, stainless steel
11.40210.001	Scheidenspekulum Cusco Schweizer Mod.Gr. 1, Edelstahl	Vaginal specula, Cusco Swiss model no.1, stainless steel
11.40220.001	Scheidenspekulum Cusco Schweizer Mod.Gr. 2, Edelstahl	Vaginal specula, Cusco Swiss model no.2, stainless steel
11.40230.001	Scheidenspekulum Cusco Schweizer Mod.Gr. 3, Edelstahl	Vaginal specula Cusco Swiss model no.3, stainless steel

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Spiegel, laryngeal** Mirrors Laryngeal
Zweckbestimmung / Intended use:	Zur instrumentellen Inspektion des Kehlkopfes (indirekte Laryngoskopie). For instrumental inspection of the larynx (indirect laryngoscopy).

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: 4030155KaWe1105Z8

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
Spiegel, laryngeal

List of devices accompanying the declaration of conformity
Mirrors Laryngeal

Artikel-Nr. / Ref	Bezeichnung	Denomination
11.30100.081	Kehlkopfspiegel Gr. 00 8 mm Durchmesser	Larynx mirror size 00,Ø8 mm
11.30100.101	Kehlkopfspiegel Gr. 0 10 mm Durchmesser	Larynx mirror size 0,Ø 10 mm
11.30100.121	Kehlkopfspiegel Gr. 1 12 mm Durchmesser	Larynx mirror size 1, Ø12 mm
11.30100.141	Kehlkopfspiegel Gr. 2 14 mm Durchmesser	Larynx mirror size 2, Ø14 mm
11.30100.161	Kehlkopfspiegel Gr. 3 16 mm Durchmesser	Larynx mirror size 3, Ø16 mm
11.30100.181	Kehlkopfspiegel Gr. 4 18 mm Durchmesser	Larynx mirror size 4, Ø 18 mm
11.30100.201	Kehlkopfspiegel Gr. 5 20 mm Durchmesser	Larynx mirror size 5, Ø 20 mm
11.30100.221	Kehlkopfspiegel Gr. 6 22 mm Durchmesser	Larynx mirror size 6, Ø 22 mm
11.30100.241	Kehlkopfspiegel Gr. 7 24 mm Durchmesser	Larynx mirror size 7, Ø 24 mm
11.30100.261	Kehlkopfspiegel Gr. 8 26 mm Durchmesser	Larynx mirror size 8, Ø 26 mm
11.30100.281	Kehlkopfspiegel Gr. 9 28 mm Durchmesser	Larynx mirror size 9, Ø 28 mm
11.30100.301	Kehlkopfspiegel Gr. 10 30 mm Durchmesser	Larynx mirror size 10, Ø 30mm

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Spritze, Ohr** Syringe, Ear
Zweckbestimmung / Intended use:	HNO-Spritze zum Spülen des äußeren und mittleren Gehörgangs. ENT-syringe for irrigation of the external and middle ear canal.

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: 4030155KaWe1101YY

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

Spritze, Ohr

List of devices accompanying the declaration of conformity

Syringe, Ear

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
11.05105.002	Ganzmetallspritzen mit 2 Kanülen, 50 ccm	All-metalsyringe, with 2 cannulae,50 ccm
11.05110.002	Ganzmetallspritze mit 2 Kanülen, 100 ccm	All-metalsyringe with 2 cannulae,100 ccm
11.05115.002	Ganzmetallspritze mit 2 Kanülen, 150 ccm	All-metalsyringe with 2 cannulae,150 ccm
11.05901.001	Wundkanüle konisch mit Gewinde M6, aus Metall	Wound cannula, conical, with thread M6, of metal
11.05902.001	Klistierkanüle oliv mit Gewinde M6, aus Metall	Enema cannula, olive-shaped, with thread M6, of metal
11.05903.001	Metallschutzschild mit Ansatz	Protective shield of metal with connection

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Staubinde, Gurt** Tourniquets, Strap
Zweckbestimmung / Intended use:	Zum Stauen des venösen Blutflusses für die venöse Blutabnahme. To staunch venous blood flow for venous blood sampling.

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: 4030155KaWe1203Z9

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

Staubinde, Gurt

List of devices accompanying the declaration of conformity

Tourniquets, Strap

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
12.10110.031	KaWe-Venenstauer "easy clic" blau/weiß + Multifunktionsclip	KaWe-tourniquet "easy clic" blue/white with quick

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Batterieladegerät** Battery Charger
Zweckbestimmung / Intended use:	Ladestation zur Ladung von KaWe Ladegriffen des Typs „2,5 V“ und „3,5 V“ mit NiMH- oder Li-Ion-Ladebatterie. Charging station for charging KaWe charging handles of type "2.5 V" and "3.5 V" with NiMH or Li-Ion charging battery.

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: 4030155KaWe1204ZB

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
Batterieladegerät

List of devices accompanying the declaration of conformity
Battery Charger

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
12.80005.002	MedCharge 4000 Ladestation kpl. mit Netzteil	MedCharge 4000 battery charger compl. with mains adaptor

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Lupe, Operation** Magnifiers Operating
Zweckbestimmung / Intended use:	Zubehör zur KaWe-Kopfleuchte für eine vergrößerte Betrachtung des Untersuchungsfeldes. Accessory to the KaWe headlamp for a magnified view of the examination field.

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: 4030155KaWe1201Z5

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

Lupe, Operation

List of devices accompanying the declaration of conformity

Magnifiers Operating

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
12.89342.342	Binokularlupe 2,5 x 340 mm für LED-Kopfleuchte	Binocularmagnifying glasses 2.5 x 340mm for LEDHead lamp
12.89342.422	Binokularlupe 2,5 x 420 mm für LED-Kopfleuchte	Binocularmagnifying glasses 2.5 x 420mm for LEDHead lamp
12.89343.342	Binokularlupe 3,5 x 340 mm für LED-Kopfleuchte	Binocularmagnifying glasses 3.5 x 340mm for LEDHead lamp
12.89343.422	Binokularlupe 3,5 x 420 mm für LED-Kopfleuchte	Binocularmagnifying glasses 3.5 x 420mm for LEDHead lamp

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**STIRNLEUCHTE** Headlights
Zweckbestimmung / Intended use:	Beleuchtungsmittel für ärztliche Untersuchungen, dazu bestimmt während der Anwendung auf dem Kopf getragen zu werden. Illuminator for medical examinations, intended to be worn on the head during use.

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: 4030155KaWe1201Z5

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
STIRNLEUCHTE

List of devices accompanying the declaration of conformity
Headlights

Artikel-Nr. / Ref	**Bezeichnung**	**Denomination**
12.89310.112	Kopfleuchte HiLight LED H-800 Set 1, EU	Head lampHiLight LED H-800 Set 1, EU
12.89310.122	Kopfleuchte HiLight LED H-800 Set 1, GB	Head lampHiLight LED H-800 Set 1, GB
12.89310.132	Kopfleuchte HiLight LED H-800 Set 1, US	Head lampHiLight LED H-800 Set 1, US
12.89311.212	Kopfleuchte HiLight LED H-800 Set 2, EU	Head lampHiLight LED H-800 Set 2, EU
12.89311.222	Kopfleuchte HiLight LED H-800 Set 2, GB	Head lampHiLight LED H-800 Set 2, GB
12.89311.232	Kopfleuchte HiLight LED H-800 Set 2, US	Head lampHiLight LED H-800 Set 2, US
12.89312.312	Kopfleuchte HiLight LED H-800 Set 3, EU	Head lampHiLight LED H-800 Set 3, EU
12.89312.322	Kopfleuchte HiLight LED H-800 Set 3, GB	Head lampHiLight LED H-800 Set 3, GB
12.89312.332	Kopfleuchte HiLight LED H-800 Set 3, US	Head lampHiLight LED H-800 Set 3, US

EU-KONFORMITÄTSERKLÄRUNG

EU-DECLARATION OF CONFORMITY

Hersteller / Manufacturer:	Kirchner & Wilhelm GmbH + Co KG Eberhardstr. 56 71679 Asperg Deutschland / Germany
Produktfamilie / Product family:	**Leuchte, sonstige** Light, other
Zweckbestimmung / Intended use:	Diagnostikinstrument zur Ausleuchtung der zu untersuchenden Stelle z. B. Mundhöhle, Hautoberfläche. Diagnostic instrument for illuminating the area to be examined, e.g. oral cavity, skin surface.

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: 4030155KaWe1202Z7

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

Asperg, 2021-04-29

R. Kirchner-Gottschalk
Geschäftsleitung / President

Liste der zur Konformitätserklärung zugehörigen Produkte
Leuchte, sonstige

List of devices accompanying the declaration of conformity
Light, other

Artikel-Nr. / Ref	Bezeichnung	Denomination
12.05100.071	Diagnostikleuchte, weiß Metall, mit Druckknopf , VE = 5 St.	diagnostic lamp, white, metal with push-button, PU = 5 pcs.
12.05302.021	KaWe DIALIGHT XL Diagnostik- leuchte, 2,5 V, night	KaWe DIALIGHT XL diagnostic lamp, 2.5V, night
12.05302.231	KaWe DIALIGHT XL Diagnostik- leuchte, 2,5 V, sky	KaWe DIALIGHT XL diagnostic lamp, 2.5V, sky
12.05401.014	Cliplight Diagnostikleuchte LED, inkl. Batterien, rot	Cliplightdiagnostic lamp LED, incl. batteries, red
12.05401.024	Cliplight Diagnostikleuchte LED, inkl. Batterien, schwarz	Cliplightdiagnostic lamp LED, incl. batteries, black
12.05401.054	Cliplight Diagnostikleuchte LED, inkl. Batterien, gelb	Cliplightdiagnostic lamp LED, incl. batteries, yellow
12.05401.094	Cliplight Diagnostikleuchte LED, inkl. Batterien, lila	Cliplightdiagnostic lamp LED, incl. batteries, violet
12.05401.234	Cliplight Diagnostikleuchte LED, inkl. Batterien, blau	Cliplightdiagnostic lamp LED, incl. batteries, blue
12.05401.264	Cliplight Diagnostikleuchte LED, inkl. Batterien, grau	Cliplightdiagnostic lamp LED, incl. batteries, grey
12.05411.004	Cliplight Diagnostikleuchte LED, inkl. Batterien, SET	Cliplightdiagnostic lamp LED, incl. batteries, SET
12.05601.012	med.lux Pen, rot	med.lux Pen, red
12.05601.022	med.lux Pen, schwarz	med.lux Pen, black
12.05601.032	med.lux Pen, blau	med.lux Pen, blue
12.05601.042	med.lux Pen, grün	med.lux Pen, green
12.05601.092	med.lux Pen, lila	med.lux Pen, violet
12.05601.162	med.lux Pen, silber	med.lux Pen, silver

S-24664	Diagnostikleuchte, weiß Metall, mit Druckknopf , VE = 1 St.	diagnostic lamp, white, metal with push-button, PU = 1 pcs.

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

MINISTERUL SĂNĂTĂȚII
AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ МОЛДОВА
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, muh. Chișinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: office@ansp.gov.md

DOCUMENTAȚIE MEDICALĂ / Медицинская документация
FORMULAR / Форма Nr. 303-2/e
APROBAT DE MS al RM / Утверждена МЗ РМ 31.10.11 Nr. 828

Centrul de Încercări de laborator acreditat de către
Centrul Național de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный
Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LI-044 din 17.02.2018 valabil până la 16.02.2022

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. 5033

Санитарное заключение для пищевых и непищевых продуктов

din/от " 20. " 12. a./г. 2021

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Cutii din carton

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

Regulamentului sanitar privind materialele şi obiectele destinate să vină în contact cu produsele alimentare aprobat prin HG nr.308 din 29.04.2011, GOST 7376-89, GOST 9142-90, GOST 13512-91, GOST 13511-2006, GOST 13516-86, GOST 13513-86

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

„ATGAIA-SU" SRL , Republica Moldova; ООО "ДУНАПАК ТАВРИЯ", Ucraina – furnizor materie primă

Destinatarul avizului sanitar / *получатель санитарного заключения*

„ATGAIA-SU" SRL, Moldova, Chișinău, bd. Dacia, 19, ap.11

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr.201 din 20.11.2020, facturi, certificate de calitate, declarație de conformitate, aviz sanitar nr.P-2363/2019 din 31.07.2019, raport a încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

(a enumera documentele anexate / Inscrie, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)*	**Normativul sanitar /** *санитарный норматив*

conform raportului încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

Domeniu de utilizare / *Область применения:* ambalaj, inclusiv produse alimentare

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
producerea, plasarea pe piață în condițiile respectării legislației în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 31 decembrie 2024

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ
Nicolae JELAMSCHI
(numele, prenumele/ Ф.И.О.)

L.Ș. (semnătura / подпись)

SP 10-XVI-09

ANSP/HAO3

0004158 O3

ex:Șt.Constantinovici
tel: 574 679

CERTIFICATO CE

Certificato n. 1974/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

mantiene nello stabilimento di:

47122 FORLI' (FC) - VIA GRAMADORA 12/14 (ITA) - Italy

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Gel per ultrasuoni e lubrificante sterile

Accessori per elettrobisturi

Modd. come da documento "Allegato al Certificato CE no. 1974/MDD - Elenco dei Dispositivi" rev. 9 del 07/10/2020, valido solo se provvisto di timbro IMQ; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM17-0017248-01; DM19-0038073-01; DM20-0056104-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2017-11-18
Data aggiornamento:	2020-10-07
Sostituisce:	2020-04-06
Data scadenza:	2022-11-17

Giorgi Fulvio
IMQ

DocuSign

EC CERTIFICATE

Certificate No 1974/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factory of:

47122 FORLI' (FC) - VIA GRAMADORA 12/14 (ITA) - Italy

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Sterile ultrasound transmission gel and sterile lubricating gel

Accessories for electrosurgical units

Type ref. as to document "Annex of EC Certificate no. 1974/MDD - Device List" rev. 9 dated 2020/10/07 valid only if provided with IMQ stamp; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:
DM17-0017248-01; DM19-0038073-01; DM20-0056104-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2017-11-18
Updated:	2020-10-07
Substitution Date:	2020-04-06
Expiry Date:	2022-11-17

Giorgi Fulvio
IMQ

DocuSign

Allegato al Certificato CE n. 1974/MDD- Elenco dei Dispositivi

EC Certificate Annex 1974/MDD - Device List

rev. 9 del/of **2020/10/07**

Categoria di dispositivo: Device category:	**Gel per ultrasuoni e lubrificante sterile** Sterile ultrasound transmission gel and sterile lubricating gel
Modello/i: Model(s):	**Super Sterigel;** **Lubri Supergel sterile.**
Marca/Marche: Trade mark(s):	**Ceracarta**
Altre informazioni rilevanti: Other relevant data:	**Dispositivi medici in classe IIA** Class IIA Medical Devices

Timbro IMQ
IMQ Stamp

2020-10-07

Allegato al Certificato CE n. 1974/MDD- Elenco dei Dispositivi

EC Certificate Annex 1974/MDD - Device List

rev. 9 del/of **2020/10/07**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units	
Modello/i: Model(s):	**0013447**	**PIASTRA ELETTROBISTURI MONOPARTITA ADULTI 2125** ELECTROSURGICAL PLATE 1 ZONE ADULT 2125
	0013448	**PIASTRA ELETTROBISTURI BIPARTITA ADULTI 2500** ELECTROSURGICAL PLATE 2 ZONE ADULT 2500
	0013449	**PIASTRA MONOPARTITA PEDIATRICA 2225** ELECTROSURGICAL PLATE 1 ZONE PAEDIATRIC 2225
	0013450	**PIASTRA MONOPARTITA NEONATALE 2425** ELECTROSURGICAL PLATE 1 ZONE NEWBORN 2425
	0013451	**PIASTRA BIPARTITA PEDIATRICA 2600** ELECTROSURGICAL PLATE 2 ZONE PAEDIATRIC 2600
	0013452	**PIASTRA BIPARTITA NEONATALE 2700** ELECTROSURGICAL PLATE 2 ZONE NEWBORN 2700
	0014986	**PIASTRA AD BIPARTITA CAVO3MT. 2500/C-12** ELECTROSURGICAL PLATE 2 ZONE ADULT 3MT.CABLE 2500/C-12
	0015306	**PIASTRA BIPARTITA NEONATALE +CAVO 2700/C-12** ELECTROSURGICAL PLATE 2 ZONE NEWBORN +CABLE 2700/C-12
	0015370	**PIASTRA MONOPARTITA AD+CAVO 2125/C-00** ELECTROSURGICAL PLATE 1 ZONE ADULT + CABLE 2125/C-00
	0015402	**PIASTRA AD.+CAVO 2125/C-10** ELECTROSURGICAL PLATE ADULT+CABLE 2125/C-10
	0015986	**PIASTRA PEDIATRICA.+CAVO 2600 C/12** ELECTROSURGICAL PLATE PAEDIATRIC.+CABLE 2600 C/12
	0016041	**PIASTRA BIPARTITA AD+CAVO 2500/C-00** ELECTROSURGICAL PLATE 2 ZONE ADULT+CABLE 2500/C-00
	0016090	**PIASTRA BIPARTITA NEONATALE+ CAVO 2700/C-00** ELECTROSURGICAL PLATE 2 ZONE NEWBORN+ CABLE 2700/C-00
	0016295	**PIASTRA BIPARTITA ADULTI + CAVO 5 MT. 2500 /C/12/05** ELECTROSURGICAL PLATE 2 ZONE ADULT + CABLE 5 MT. 2500 /C/12/05
	0016490	**PIASTRA CAVO 5MT.2500-C-00** ELECTROSURGICAL PLATE 5MTCABLE .2500-C-00
	0016735	**PIASTRA MONOPARTITA NEONATALE 2425-C/00** ELECTROSURGICAL PLATE 1 ZONE NEWBORN 2425-C/00
	0016736	**PIASTRA MONOPARTITA PEDIATRICA 2225-C/00** ELECTROSURGICAL PLATE 1 ZONE PAEDIATRIC 2225-C/00
	0016994	**PIASTRA BIPARTITA PEDIATRICA 2600-C/00** ELECTROSURGICAL PLATE 2 ZONE PAEDIATRIC 2600-C/00
Altre informazioni rilevanti: Other relevant data:	**Dispositivi medici in classe IIB** Class IIB Medical Devices	

Timbro IMQ
IMQ Stamp

2020-10-07

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

mantiene nello stabilimento di:

47122 FORLI' (FC) - VIA GRAMADORA 12/14 (ITA) - Italy

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento "Allegato al Certificato CE no. 1976/MDD - Elenco dei Dispositivi" rev.0 del 07/10/2020, valido solo se provvisto di timbro IMQ; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:
DM17-0017248-01; DM20-0056104-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2017-11-18
Data aggiornamento:	2020-10-07
Sostituisce:	2017-11-18
Data scadenza:	2022-11-17

Giorgi Fulvio
IMQ

DocuSign

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factory of:

47122 FORLI' (FC) - VIA GRAMADORA 12/14 (ITA) - Italy

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Medical recording chart paper

Type ref. as to document "Annex of EC Certificate no. 1976/MDD - Device List" rev. 0 dated 2020/10/07 valid only if provided with IMQ stamp; this annex is integral and substantial part of this certificate.

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01; DM20-0056104-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2017-11-18
Updated:	2020-10-07
Substitution Date:	2017-11-18
Expiry Date:	2022-11-17

Giorgi Fulvio
IMQ

DocuSign

Allegato al Certificato CE n. 1976/MDD- Elenco dei Dispositivi

EC Certificate Annex 1976/MDD - Device List

rev. 0 del/of **2020/10/07**

Categoria di dispositivo: Device category:	**Carte per registrazione ad uso medico** Medical recording chart paper
Modello/i: Model(s):	**22.01 Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi);** **21.01 Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi);** **32.01 Schede e dischi stampati medicali.**
Marca/Marche: Trade mark(s):	**Ceracarta**
Altre informazioni rilevanti: Other relevant data:	**Dispositivi medici in classe I con funzione di misura (IM)** Medical Devices in class I with measuring function (IM)

Timbro IMQ
IMQ Stamp

2020-10-07

www.imq.it

CISQ is a member of

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THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

www.imq.it

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CSQ
www.imq.it

ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale.
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years.

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com

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CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)
VIA GRAMADORA 12/14 - 47122 FORLI' (FC)
has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2020 - 09 - 29**
Expires on: ***2023 - 10 - 07***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

CISQ is a member of

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CERTIFICATO N.
CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

Organismo di Certificazione Federato CISQ
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FEDERAZIONE CISQ

www.cisq.com

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CISQ is the Italian Federation of management system Certification Bodies.

www.imq.it

CISQ is a member of

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www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ALLEGATO N. **9124.CRC4-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ

Organismo di Certificazione Federato CISQ
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FEDERAZIONE CISQ

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CISQ is the Italian Federation of management system Certification Bodies.

CISQ is a member of

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CSQ
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ALLEGATO N. **9124.CRC4-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA
THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
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Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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CISQ is the Italian Federation of management system Certification Bodies.

CERACARTA S.p.A.

ISO 9001:2008 EN ISO 13485:2012

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipments.
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking system, lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

Messrs

Medicines and Medical Devices Agency

Forlì, 3rd August 2022

We, CERACARTA SPA V having a registered office at Via Secondo Casadei 14,47122 Forlì(FC)-Italy, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **Authorized representative** in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

Manufacturer: **Ceracarta S.p.A.**

Address: **Via Secondo Casadei, 14 47122 Forlì - ITALY**

DECLARES

that

THE RECORDING "THERMAL" AND/OR "INK" PAPERS IN THE MEDICAL FIELD for "ECG", "EEG","CTG" and papers for laboratory tests (including the model M 1911 A),

identified and classified in the

Technical file ,comply with the directive about medical devices (DIRECTIVE 93/42/CEE as amended by 2007/47/EC).

In addition to this, we precise that:

- according to the Directive 93/42/EEC the listed products are medical devices belonging to class I with function of measure.
- they are subject to the regulations of the Attachment I of the above mentioned directive;
- the evaluation of the device was in accordance with Annex V of that Directive, by the certified body IMQ S.p.A. – CE0051;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2008

EN ISO 13485:2012

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"ECG GEL / ECO SUPERGEL ."** ***(BASIC UDI-DI 8059170GC004NN)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies;
- the Dispositive in object must be esclusively used together with electro-medical instruments for recording, diagnosis and therapy, which base their functioning upon the measuring of energy flows of electric, magnetic and ultrasound type;
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015

EN ISO 13485:2016

CERACARTA® S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **TOP TRACE ECG ELECTRODES *(BASIC UDI-DI 8059170EL001PR)***,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.

In addition:

- the device is tested according to the voluntary Association for the Advancement of Medical Instrumentation (AAMI) standard requirements for electrical performance for disposable ECG electrodes (ANSI/AAMI EC 12:2000) and test results meet or exceed these performance standards.
- the device is tested and it is found to be acceptable for use,according to:

UNI EN ISO 10993-1:"Biological evaluation of medical devices" ;

UNI EN ISO 10993-5 :"Biological evaluation of medical devices :tests for in vitro cytotoxicity";

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015 EN ISO 13485:2016

CERACARTA® S.p.A.

UNI EN ISO 10993-10 :"Biological evaluation of medical devices :tests for irritation and sensitization".

• Ceracarta does not use any latex/PVC materials or ingredients in the manufacturing of our electrodes;

• Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro

CERACARTA s.p.a.
Alessandro Bandini

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015

EN ISO 13485:2016

CERACARTA S.p.A.

DECLARATION OF CONFORMITY

Forlì, 3rd August 2022

The writing company Ceracarta S.p.a. located in Via Secondo Casadei n° 14, 47122 Forlì, manufacturer of the products named , **"COMPATIBLE PAPER FOR SONY UPP 110 S / HG / HD ROLLS", (BASIC UDI-DI 8059170CA001LN)**,identified and classified in the technical file,declares under its own responsibility that such devices satisfies all the requirements of MDR 2017/745 , about medical devices and in particular that:

- in accordance with enclosure VIII-section III of the MDR the Dispositives in object must be considered as belonging to Class I;
- the Dispositives in object satisfy the essential requirements as in enclosure I of MDR 2017/745;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure II of the MDR;
- such documentation is available at the headquarters of Ceracarta , for any reference by the entitled bodies.
- Ceracarta S.p.A. has implemented a quality system in accordance with the regulations UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485:2016.

The president

CERACARTA SPA
Bandini Alessandro
CERACARTA s.p.a.

Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forlì ITALY
Tel: +39.0543780055 Fax: +39.0543781404
http://www.ceracarta.it info@ceracarta.it

ISO 9001:2015 EN ISO 13485:2016

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPC-21L
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Color Printing Pack
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02261

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110S
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02266

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HG
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-04

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02267

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

SONY

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPP-110HD
2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium
3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration: Thermal Print Media
5. The object of the declaration described above is in conformity with:
   2017/745 (Medical Device Regulation)
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
   Medical: EN 60601-1:2006 + A1:2013
7. Where applicable, the notified body (name and number), description of intervention and certificate:
8. Additional information:
   - Classification: Class I, MDR Annex VIII
   - Basic UDI-DI: 4901780PrintMediaWR
   - Manufacturer SRN: JP-MF-000014553
   - Authorised Representative SRN: BE-AR-000007876
   - Intended Purpose: Print media for Sony's medical printer
   - Accessory(ies): -
   - Note(s): -

Signed for and on behalf of: Sony Corporation

Tokyo, 2021-11-10

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2021EU02280

Sony Corporation
1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following manufacturing sites:

No.	Location
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland
/03	Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Bevollmächtigter

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

Certificate Holder: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

including the locations according to annex

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-09 until 2023-07-08.
First certification 2017

2022-05-18 (Change)

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	c/o Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	c/o Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	c/o Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing of ventilators and ventilator systems
/04	c/o Hamilton Medical AG Industriepark Vial 4 7013 Domat/Ems Switzerland	Manufacture of ventilator sensors and tubing systems

2022-05-18 (Change)

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

CERTIFICATE

No. 490346

LL-C Certification

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

MEDIZINTECHNIK seit 1890 KaWe

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

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

S 3137

validity code **11244C52-6E6**
Check the validity of this certificate using this code at www.ll-c.info

SAFETY · SECURITY · ENVIRONMENT · QUALITY LL-C Certification

www.ll-c.net

Product catalog

This document reflects your selection of products from the Hamilton Medical online product catalog.
The content is based on the following parameters:

Creation Date:	**17 August 2022**
Country settings:	**International**
Your selection:	**Accessories & consumables** • Oxygen sensors
Search keywords	**396200**

The online product catalog is subject to change without notice. The latest and most comprehensive product information is available online.

Legend

Single use

Reusable

Autoclavable


Adult


Pediatric


Neonatal


The packaging unit of each single product is marked within this box icon.

Oxygen sensors

Product		Description
	**396200** 1	**Oxygen sensor** For ventilator: HAMILTON-C6/C3/C2/C1/T1/MR1 GTIN: 07630002801126 Corresponding part number for initial device configuration **10102092** HAMILTON-C1 **10105900** HAMILTON-T1 **10103232** HAMILTON-MR1

HAMILTON MEDICAL

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 (0)58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com