# Zertifikat

**mdc medical device certification GmbH**
bescheinigt hiermit, dass das Unternehmen

**Karl Kaps GmbH & Co. KG**
**Schulstraße 57**
**35614 Asslar**
**Deutschland**

im Geltungsbereich

**Entwicklung, Herstellung und Vertrieb von**
**Geräten für die Medizin, Operations- und Diagnosemikroskopen**
**sowie Kolposkopen**

ein

## Qualitätsmanagementsystem

eingeführt hat und anwendet.

Ein Audit von mdc hat den Nachweis erbracht, dass dieses Qualitätsmanagementsystem die Forderungen der folgenden Norm erfüllt:

## DIN EN ISO 13485

Medizinprodukte – Qualitätsmanagementsysteme –
Anforderungen für regulatorische Zwecke

DIN EN ISO 13485:2016 + AC:2016 - EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

| | |
|---|---|
| Gültig ab | 2020-12-06 |
| Gültig bis | 2023-12-05 |
| Registrier-Nr. | D1373600006 |
| Bericht-Nr. | P20-01671-187680 |
| Berlin, den | 2020-11-30 |

Leiter Zertifizierungsstelle

Digitally signed by Gherman Irina
Date: 2023.11.09 13:09:54 EET
Reason: MoldSign Signature
Location: Moldova

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

KARL KAPS GmbH & Co. KG
Schulstrasse 57 • D-35614 Asslar
Germany

Phone: +49 (0)6441 807040
Fax: +49 (0)6441 85985

# EU-Konformitätserklärung
# EU-Declaration of Conformity

Wir, KARL KAPS GmbH & Co. KG, erklären in alleiniger Verantwortung, dass die unten beschriebenen Medizinprodukte allen Anforderungen der nachstehenden **Verordnung** und den damit verbundenen harmonisierten Normen entsprechen: **(EU) 2017/ 745)**

We, KARL KAPS GmbH & Co. KG, declare on our own responsibility that the medical devices discribed below are in compliance with requirements of following **regulation** and their related harmonized standards: **(EU) 2017/ 745)**

| | |
|---|---|
| **Single Registration Number** | DE-MF-000005020 |
| **Produktbezeichnung / Product name** | Stereo Operations-Mikroskop<br>Stereo operating microscope |
| **Artikelnummer und Typ / Articel number and type** | Siehe Anhang / See Annex |
| **Basis UDI-DI/ Basic UDI-DI** | 426074147SOM22-32-62-827C |
| **Zweckbestimmung / Intended use** | Mikroskop für Operation und Diagnose/<br>Microscope for surgery and diagnosis |
| **UMDNS classification** | 12-539 |
| **Konformitätsbewertungsverfahren / Conformity assessment procedure** | Gemäß: EU/ 2017/ 745: Anhang II und III /<br>according: EU/ 2017/ 745: Annex II and III |
| **Risikoklasse / Risk class** | I |
| **Klassifizierungsregel / Classification rule** | Rule 13 Annex VIII (EU) 2017/745 |

| Ort, Datum/ Place, date | Name und Funktion/ Name and function |
|---|---|
| Asslar, 26.05.2021 |  <br>Holger Kaps, CEO |

Anhang/ Annex

| Artikelnummer / Articel number | Typ | Type |
|---|---|---|
| SOM 22 / 32 / 62 | Kaps 900 | Kaps 900 |
| SOM 22 / 32 / 62 | KAPS 1100 | KAPS 1100 |
| SOM 22 / 32 / 62 | Kaps 1200 | Kaps 1200 |
| SOM 22 / 32 / 62 | Kaps 1300 | Kaps 1300 |
| SOM 22 / 32 / 62 | Kaps 1400 | Kaps 1400 |
| SOM 22 / 32 / 62 | Kaps 1450 | Kaps 1450 |
| SOM 22 / 32 / 62 | HNO Untersuchung | ENT examination |
| SOM 22 / 32 / 62 | Kaps Pro ENT high end manual | Kaps Pro ENT high end manual |
| SOM 22 / 32 / 62 | Kaps Pro ENT motorized | Kaps Pro ENT motorized |
| SOM 22 / 32 / 62 | Ophthal Basic | Ophthal Basic |
| SOM 22 / 32 / 62 | Ophthal basic+ | Ophthal basic+ |
| SOM 22 / 32 / 62 | Ophthal Advanced | Ophthal Advanced |
| SOM 82 | Tischgerät | table device |
| | Inkl. Zubehör | Incl. accessories |

# EG Konformitätserklärung

*(Richtlinie 93/42/EWG)*

# EC Declaration of Conformity

*(Directive 93/42/EEC)*

| | |
|---|---|
| **Hersteller/manufacturer:** | Karl Kaps GmbH & Co. KG |
| **Anschrift/address:** | Schulstrasse 57<br>35614 Asslar<br>Germany |
| **Produktbezeichnung/ Produktgruppe:** | Accessories I |
| **Typen/types:** | Tubes, Oculars, Objectives (non-electrical), Beam Splitter, Magnification Units (non electrical) |
| **Klasse/class:** | I |

Wir erklären hiermit, dass das hier beschriebene Medizinprodukt mit den Forderungen der Richtlinie 93/42/EWG, Anhang I übereinstimmt. Der Nachweis hierzu wurde mit dem Konformitätsbewertungsverfahren nach Anhang VII geführt.

We declare that the above listed medical product conforms to the relevant provisions of the actual EC Council Directive 93/42/EEC Annex I. The conformity assessment procedures was carried out according to Annex VII.

**Referenz- Nr./reference no.:**
EN 60601-1:2005 (ed. 3)
DIN EN 980: 2008-08
ISO 11884-1-2006
EN 60601-1-2:2007 (ed. 3)
EN 60601-1-6:2007
DIN EN ISO 13485: 2010-01
DIN EN ISO 14971: 2009-10
EN ISO 9001:2008
Richtlinie 93/42/EWG

CE

| | |
|---|---|
| Aussteller/ issued by: | Karl Kaps GmbH & Co. KG |
| Ort, Datum/ place, date: | Asslar, 06.04.2021 |
| Rechtsverbindliche Unterschrift:<br>Signature of authorized person: | KARL KAPS GmbH & Co.KG<br>Schulstrasse 57 • D-35614 Asslar<br>Phone: +49(0)6441 80 70 40<br>Fax: +49(0)6441 85 98 5<br>Mail: info@kaps-optik.de<br>Internet: www.kaps-optik.de |

Holger Kaps, CEO

# EG Konformitätserklärung für Medizinprodukte

Declaration of CE Conformity for Medical Products

| | |
|---|---|
| Herstellers / Name of manufacturer: | GREINER GmbH<br>D-74385 Pleidelsheim, Wettestraße 1<br>https://www.greiner-gmbh.de |
| SRN | DE-MF-000007660 |
| Produkt / Product | medseat |
| Basis UDI-DI | 406609847177 |
| Artikelbeschreibung /Description: | *Aktives Medizin-Produkt:*<br>Untersuchungs- und Behandlungsstuhl mit mechanisch oder elektromechanisch verstellbarem Unterteil, Oberteil wahlweise mit Gasfeder oder elektromechanisch verstellbar.<br>*Active medical device:*<br>Examination and treatment chair with mechanically or electrical height adjustment. Upper part optionally via gas spring or electromechanically adjustable. |
| Modelle / models | 461 – 474<br>(mit elektrischen Komponenten / with electrical components) |
| Klassifizierung nach Verordnung (EU) 2017/745, Anhang VIII Kapitel III, Regel 1 und 13<br>Classification according regulation (EU) 2017/745, annex VIII, chapter III rule 1 and 13 | Risikoklasse I<br><br>Hazard class I |

Wir versichern in alleiniger Verantwortung, dass die von dieser Erklärung erfassten Produkte, in der gelieferten Ausführung den Anforderungen der Verordnungen (EU) 2017/745; 2011/65/EU entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen.

We declare under our sole responsibility that the products covered by this declaration, as supplied, comply with the requirements of regulations (EU) 2017/745; 2011/65/EU. The products are marked with the CE mark.

Gültig bis / valid until: 2026-05-26

CE

| Wegmann, PRRC | 2021-07-08 | |
|---|---|---|
| Name, Funktion | Datum | Unterschrift |

# EG Konformitätserklärung
# EC Declaration of conformity

dantschke
intelligent medical systems

| | |
|---|---|
| Wir/We | dantschke Medizintechnik GmbH & Co. KG |
| Anschrift/Address | Apelsteinallee 3<br>D-04416 Markkleeberg |
| Land/Country | Deutschland/Germany |

erklären in alleiniger Verantwortung, dass das Produkt
declare under sole responsibility, that the product

Bezeichnung/Name **HNO Behandlungseinheit MEDICENTER / ENT Treatment Unit MEDICENTER**

| Typ / Model | Seriennummer größer / Later than Serial-No. |
|---|---|
| MEDICENTER Futura | MC F67LG 346 04 19 |
| MEDICENTER Otlaphari | MC O50 094 04 19 |
| MEDICENTER Intra | MCI 50P 368 04 19 |
| MEDICENTER Karl Storz | MC KS 01 097 _ _19 |

mit folgenden, untereinander kombinierbaren Komponenten
with following, themselves variable components

Ohrspüleinrichtung, Drucklufteinrichtung, Absaugeinrichtung , Ohrspüleinrichtung, Kaltlichteinrichtung, Optikvorwärmung, Spiegelvorwärmung
Ear rinsingfacilities, Compressedairfacilities, Suctionfacilities, Ear rinsing facilities, Cold lightfacilities, optics preheating, mirror preheating

die grundlegenden Anforderungen der Richtlinie **RL 93/42/EWG** erfüllt,
fulfils the fundamental requirements of the guidelines fulfilled,

mit den erstellten Dokumentationen übereinstimmt und damit den Bestimmungen entspricht.
coincides with the generated documentation, and thus complies with the provisions.

**Konformitäts Bewertungsverfahren:** **nach Anhang II (ohne 4)**
Conformity evaluation method: **as attachment II without 4**

Das Produkt entspricht der Risikoklasse: IIa
the product equates to the risk class

Die zuständige benannte Stelle für das Produkt und für die Zertifizierung des QM-Systems ist die Notified body for product and quality management system is

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH (0633 )
Dovestrasse 6
10587 Berlin

Gültigkeit des Produktzertifikates:

Markkleeberg, 02.04.2019
Ort und Datum der Ausstellung
Place and date of issue

Geschäftsführer/ CEO
Dipl.-Ing (FH). Denis, Robel
Name und Unterschrift des Befugten
Name and signature of authorized person

# Declaration of Conformity

Validity of this declaration from 21.05.2013 to 26.05.2024

Manufacturer: **Micromed Medizintechnik GmbH**

Address: **Eisenbahnstraße 84, 78573 Wurmlingen**

Description, type/model: **Electrosurgery unit – Electrosurgery accessory**

Art-No.: **see appendix**

Classification: **Class IIb Products acc. to annex IX, regulation 9 of the 93/42 EWG**

UMDNS- und GMDN-Code: **11-490, 32811**

**Selected conformity procedure:**

According to annex II.3 for class IIa/IIb products of the European Device Directive 93/42/EWG for medical devices. We hereby confirm that the above mentioned products meet the essential requirements of the European Device Directive 93/42/EWG for the regulation of medical devices in accordance with the German Medical Products Regulation (MPG). The manufacturer bears the sole responsibility for issuing the declaration for conformity. All relevant documentation is being kept at the manufacturer´s office.

**Applied standards:**

EN 60601-1 / EN 60601-2-2

**Notified body:**

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany, shortcut 0123

**Certificates:**

EN ISO 13485:2016, Edition March 2023: Reg. Nr. Q5 034026 0020 Rev. 01 valid until 16.02.2026.
EC certificate, Edition April 2020: Reg. Nr. G1 034026 0018 Rev. 01 valid until 26.05.2024.

The validity of this declaration of conformity extends to the same period of time as the validity of the above certificate according to RL 93/42/EWG, annex II.

Subject to regular supervision.

Wurmlingen, 27.03.2021
(Date of clearance and validity)

Wurmlingen, 27.03.2021
(Place and time of issue)

Eduard Steidle
Dipl.-Ing. Eduard Steidle, Managing Director

Issued by: QMB Dipl. Ing. Eduard Steidle

Revision-No.: 06.03.2021-05

## Appendix: Article description of Electrosurgery unit – Electrosurgery accessory

| Datum | Artikel-Nummer | Artikelbezeichnung | GMDN - Code | UMDNS - Code | MD - Klasse | Klasse | Regel |
|---|---|---|---|---|---|---|---|
| 06.05.2015 | 150-001-001 | Electrosurgery unit MD1, 50W, monopolar | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 150-003-001 | Electrosurgery unit MDIII, 80 Watt, monopolar | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 150-100-001 | Electrosurgery unit MD 100 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 150-130-001 | Electrosurgery unit RF 130 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 150-200-002 | Electrosurgery unit Touch 200 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 150-300-002 | Electrosurgery unit MDV 300 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-001-001 | Accessory Set Dental MD1 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-001-002 | Accessory Set Dermatology MD1 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-001-003 | Accessory Set Surgery MD1 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-003-001 | Accessory Set Dermatology MD3 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-003-003 | Accessory Set Surgery MD3 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-003-004 | Accessory Set Dental MD3 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-003-006 | Monopolar ENT accessory set for MD3 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-003-007 | Bipolar ENT accessory set for MD3 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-100-001 | Accessory Set Surgery MD 100 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-100-002 | Accessory Set Dermatology MD 100 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-100-004 | Accessory Set Dental MD 100 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-001 | Accessory set surgery RF-130 | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-002 | Accessory set plastic surgery RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-003 | Accessory set dermatology for RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-004 | Monopolar ENT accessory set for RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-005 | Bipolar ENT accessory set for RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-006 | ENT electrode accessory set for RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-130-007 | Complete accessory set ENT bipolar, for RF-130 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-200-001 | Accessory set surgery MDV 200 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-200-002 | Accessory set ENT for MDV 200 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-300-A02 | Accessory set for argon module | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-300-V01 | Accessory set surgery MDV touch 300 HF-unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 151-300-V02 | Accessory set neurosurgery MDV touch 300 HF-unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-811-010 | Foot switch for RF surgical units cable length 5 m, for Berchtold, Integra, Martin and Micromed units | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-811-030 | Double foot switch for RF surgical units AP certified, cable length 5 m for Berchtold, Integra, Martin and Micromed | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-811-050 | Foot switch for RF surgical units, cable length 5 m, AP certified for Berchtold, Integra, Martin & Micromed | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-821-002 | 2-Pedal footswitch, cable 5 m, with folding stainless-steel bracket for Integra, Martin & Micromed RF unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-300-002 | 2-pedal footswitch for MD100, MD300, MDV200 surgery unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 152-300-003 | 2-pedal footswitch for MDV touch 300 unit | 32372 | 11-490 | MD 1104 | IIb | 9 |
| 06.05.2015 | 156-001-001 | Argon device for surgery units: Separate device as addition electrosurgery units | 32372 | 11-490 | MD 1104 | IIb | 9 |

Wurmlingen, 27.03.2021
(Date of clearance and validity)

Wurmlingen, 27.03.2021
(Place and time of issue)
Issued by: QMB Dipl. Ing. Eduard Steidle

Dipl.-Ing. Eduard Steidle, Managing Director

Revision-No.: 06.03.2021-05

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 034026 0018 Rev. 01**

**Manufacturer:** **Micromed Medizintechnik GmbH**
Eisenbahnstraße 84
78573 Wurmlingen
GERMANY

**Product Category(ies):** **HF-surgery units, accessories, surgical instruments, suture and non-active orthopaedic implants**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713175715

**Valid from:** 2020-04-27
**Valid until:** 2024-05-26

**Date,** 2020-04-27

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

# Certificate

## No. Q5 034026 0020 Rev. 01

**Holder of Certificate:** **Micromed Medizintechnik GmbH**
Eisenbahnstraße 84
78573 Wurmlingen
GERMANY

**Facility(ies):** **Micromed Medizintechnik GmbH**
Eisenbahnstraße 84, 78573 Wurmlingen, GERMANY

See Scope of Certificate

**Certification Mark:**

TÜV SÜD DIN EN ISO 13485 tuvsud.com/ps-cert

**Scope of Certificate:** **Design and development, production and distribution of electrosurgical units with accessories, surgical instruments and non active implants**

**Applied Standard(s):** EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 034026 0020 Rev. 01

**Report No.:** 713276028

**Valid from:** 2023-03-21
**Valid until:** 2026-02-16

**Date,** 2023-03-21

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

FAROMED Medizintechnik

# EU-KONFORMITÄTSERKLÄRUNG
# *EU DECLARATION OF CONFORMITY*

Hersteller: *Company* **Faromed GmbH Medizintechnik** SRN: **DE-MF-000006360**

Anschrift: *Adress* **Saalmannstrasse 9**
**13403 Berlin**
**Deutschland / Germany**

Mit dieser Konformitätserklärung erklären wir in alleiniger Verantwortung, dass die folgenden Produkte die grundlegenden Sicherheits- und Leistungsanforderungen gemäß Anhang I der Verordnung (EU) 2017/745 (MDR) erfüllen.
*With this Declaration of Conformity, we declare under our responsibility, that the following listed medical devices meet the general safety and performance requirements, according to Annex I of the Regulation (EU) 2017/745 (MDR).*

| | |
|---|---|
| Produkte, Produktgruppe<br>*Product, Product group* | **Endoskopwärmer, Spiegelwärmer**<br>***Endoscope warmer, Mirror warmer*** |
| Basis UDI-DI<br>*Basic UDI-DI* | **42503208OPTIC-WARMEREX** |
| Artikelnummer, REF<br>*Articel number, REF* | **10-220, 10-201** |
| Risikoklasse<br>*Risk class* | **I** |
| Gemeinsame Spezifikationen<br>*Common Specifications* | **-** |
| Konformitätsbewertungsverfahren<br>*Conformity Assessment Procedure* | **Verordnung (EU) 2017/745 (MDR), Anhang IV**<br>***Regulation (EU) 2017/745 (MDR), Annex IV*** |

Die EU-Richtlinie 2011/65/EU ist erfüllt.
*We declare that the EU directive 2011/65/EU is fulfilled.*

**Berlin, 25.08.2021**
Ort, Datum
*City, Date*

**Jörg Seeburg, Qualified Person**
Unterzeichner, Funktion
*Signatory, Function*

Unterschrift
*Signature*

Im Auftrag der Faromed GmbH Medizintechnik.
*On behalf of Faromed GmbH Medizintechnik.*

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 011634 0208 Rev. 02

**Certificate Holder:** medela

**Medela AG**
Lättichstrasse 4b
6340 Baar
SWITZERLAND

**Certification Mark:**

**Scope of Certificate:** **Design and Development, Production, Distribution and Service of Breast Pump Systems, Breastfeeding Products, Body Fluid and Vacuum Aspirator Systems and Vacuum Assisted Wound Closure Systems**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F001274**

**Effective Date:** **2022-01-20**

**Expiry Date:** **2025-01-03**


**Date of Issue:** 2022-01-26

( Michael Ogunleye )
Manager, US Certification Body,
Medical and Health Services

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 011634 0208 Rev. 02

**Regulatory Requirements:** **Audit/Certification Criteria**

**Australia**
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

**Canada**
- Medical Device Regulations – Part 1- SOR 98/282

**Japan**
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

**United States**
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

**Facility(ies):**

Medela AG
Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Medela AG
Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
Lättichstrasse 7, 6340 Baar, SWITZERLAND


**Date of Issue:** 2022-01-26

( Michael Ogunleye )
Manager, US Certification Body,
Medical and Health Services

TÜV®

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 011634 0208 Rev. 02

**Facility Scopes:**

**Medela AG**
Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Headquarters (Administration, Resource Management) Quality Management Department (CAPA, Document Control, Change Control, Regulatory, Post Market Surveillance), Design and Development
REPs Facility ID: F001274

**Medela AG**
Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Incoming Inspection, Packaging, Warehouse Components and Finished Goods, Logistic
REPs Facility ID: F002183

**Medela AG**
Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Assembly of Health Care and Breastfeeding Devices and Assembly of Accessories Kits
REPs Facility ID: F002183

**Medela AG**
Lättichstrasse 7, 6340 Baar, SWITZERLAND

Purchasing, Supplier Quality, Customer Service including Service/ Repair
REPs Facility ID: F001274


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( Michael Ogunleye )
Manager, US Certification Body,
Medical and Health Services

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