

EG-Konformitätserklärung EC-Declaration of conformity



Anbieter:
Supplier **Ortho Medical GmbH**

Anschrift:
Address **Hauptstrasse 5
D-78589 Dürbheim**

Medizinprodukt:
Medical Device **Wiederverwendbare chirurgische Instrumente der
Risikoklasse I (siehe Anlage)
Reusable surgical instruments risk category I (see Annex)**

ab Fertigungsdatum / since manufacturing date 01.04.2021
bis Fertigungsdatum / until manufacturing date 01.04.2024

Wir erklären in alleiniger Verantwortung: Das oben beschriebene Medizinprodukte sind konform mit:
We declare under sole responsibility: The medical device described above is in conformity with:

| Dokument-Nr. Document No. | Titel Title | Ausgabe/ Ausgabedatum Edition / Date of issue |
|------------------------------|---|--|
| 93/42/EWG | Den Grundlegende Anforderungen der Richtlinie 93/42/EWG The essential requirements of Directive 93/42 / EEC | 14.06.1993 |
| 2007/47/EG | Zuletzt geändert durch Artikel 2 der Richtlinie 2007/47 vom 5. September 2007 Last updated by Article 2 of Directive 2007/47 of 5 September 2007 | 05.09.2007 |

zusätzliche Angaben / Additional information

Wir bestätigen, dass wir eine Technische Dokumentation gemäß Richtlinie 93/42/EWG nach Anhang VII erstellt haben.

Further we herewith declare that we have established a technical documentation according to MDD 93/42/EEC; annex VII

Das QM-System wird überwacht durch die Benannte Stelle Nr. 0483 MDC Medical Device Certification GmbH, Kriegerstr. 6, 70191 Stuttgart.

The QM-system according to EC Directive app. II.3 is controlled by notified body no. 0483 MDC Medical Device Certification GmbH, Kriegerstr. 6, 70191 Stuttgart.

Zertifikat EN ISO 13485;2016 Registrier-Nr. D1039700037 / Gültig ab 2022-04-02/Gültig bis 2025-04-01
Certificate EN ISO 13485;2016 Registration-No. D1039700037 / Valid from 2022-04-02/Valid until 2025-04-01

Verantwortliche Person gemäß Art. 15 MDR 2017/745 Herr Thomas Kupferschmid. The Person responsible person for regulatory provisions according Art. 15 MDR 2017/745, is Mr. Thomas Kupferschmid.

Dürbheim: 01.04.2021

Name: Thomas Kupferschmid
Position: Person responsible for the regulatory provisions according to Art. 15 MDR 2017 / 745
Yours Sincerely,



**Annex to the Declaration of Conformity
Reusable surgical instruments**

**Anlage zur Konformitätserklärung
Wiederverwendbare chirurgische Instrumente**

| Nomenklaturbezeichnung Nomenclature designation | GMDN Code | UMDNS-Code | Klasse | Regel |
|---|--------------|------------|--------|-------|
| | | | Class | Rule |
| Schneidinstrument, Knochen /Cutters, Bone | 15670 | 10-455 | I | 6 |
| Meißel, Knochen / Chisels bone | 10825 | 10-825 | I | 6 |
| Klemme/ Clamps | 34950 | 10-861 | I | 6 |
| Klemme, Arterie / Clamps artery | 34948 | 10-865 | I | 6 |
| Klemme, Schlauch/ Clamps, Tubing | 34954 | 10-875 | I | 1 |
| Clip-Applicierer / Clip Appliers | 32591 | 10-894 | I | 6 |
| Kürette / Curets | 31335 | 11-084 | I | 6 |
| Dilatator, tracheal / Dilators, Tracheal | 11263 | 11-263 | I | 6 |
| Dilatator, Uterus/ Dilators, Uterine | 11266 | 11-266 | I | 5 |
| Sezierer/ Dissectors | 11290 | 11-290 | I | 6 |
| Handbohrer/-dreher, Knochenstift / Driver/Extractors, Bone Nail-Pin | 11346 | 11-346 | I | 6 |
| Elevatorium /Elevators | 35048 | 11-504 | I | 6 |
| Feile / Files | 35559 | 11-701 | I | 6 |
| Fadeninstrument/ Filiforms | 32864 | 11-704 | I | 6 |
| Zange / Forceps | 46751 | 11-774 | I | 6 |
| Zange, Gewebe/ Forceps, Tissue | 11775 | 11-797 | I | 6 |
| Mundsperrre/ Gags | 35085 | 11-822 | I | 5 |
| Führung/ Guides | 35095 | 11-927 | I | 6 |
| Führung, Bohrer/ Guides, Drill | 11930 | 11-930 | I | 6 |
| Führung, Gigli-Säge/ Guides, Gigli Saw | 11931 | 11-931 | I | 6 |
| Messer/ Knives, | 37826 | 12-239 | I | 6 |
| Messer, Gips/ Knives, Plaster | 35140 | 12-251 | I | 6 |
| Messer, Skalpell/ Knives, Scalpel | 35141 | 12-252 | I | 6 |
| Schneidegerät, Nagel/ Clippers, Nail | 12695 | 12-695 | I | 1 |
| Nadelhalter/ Needle Holders | 12726 | 12-726 | I | 6 |
| Osteotom, orthopädisch/ Osteotomes, Orthopedic | 12845 | 12-845 | I | 6 |
| Schneidinstrument, Stift und Draht/ Cutters, Pin and Wire | 32886 | 13-041 | I | 6 |
| Sonde/ Probes | 32864 | 13-117 | I | 6 |
| Stanze/ Punches | 35541 | 13-228 | I | 6 |
| Reibahle, orthopädisch/ Reamers, Orthopedic | 45114 | 13-297 | I | 6 |
| Wundhaken/ Retractors | 45182 | 13-373 | I | 6 |
| Wundhaken, selbstsperrend/ Retractors, Self-Retaining Operating | 42600 | 13-390 | I | 6 |
| Hohlmeißelzange/ Rongeurs | 15670 | 13-416 | I | 6 |
| Führungshilfe, Knochen schneiden/ Routers, Bone Cutting | 35095 | 13-425 | I | 6 |
| Klinge, Säge/ Blades, Saw | 44984 | 13-447 | I | 6 |
| Säge/ Saws | 10520 | 13-448 | I | 6 |
| Schere/ Scissors | 16520 | 13-480 | I | 6 |
| Schere, Verband/ Scissors, Bandage | 13481 | 13-481 | I | 6 |
| Schere, Thorax/ Scissors, Thoracic | 13504 | 13-504 | I | 6 |
| Chirurgielöffel/ Scoops | 32100 | 13-508 | I | 6 |
| Schraubendreher, Knochen/ Screwdrivers, Bone | 33968 | 13-517 | I | 6 |
| Spatel/ Spatulas | 36293 | 13-645 | I | 6 |
| Spekulum, Ohr/ Specula, Ear | 35348 | 13-662 | I | 5 |
| Spekulum, Nase/ Specula, Nasal | 35350 | 13-664 | I | 5 |
| Spekulum, rektal/ Specula, Rectal | 35351 | 13-665 | I | 5 |
| Spekulum, vaginal/ Specula, Vaginal | 35352 | 13-666 | I | 5 |
| Spreizer/ Spreaders | 13709 | 13-707 | I | 6 |
| Spreizer, Gips/ Spreaders, Plaster | 13708 | 13-708 | I | 1 |
| | 13730 | 13-730 | I | 1 |
| Zangeninstrument, Knochen/ Tongs, Bone | | | I | 6 |
| Extensionseinheit/ Traction Units | 35359 | 14-105 | I | 6 |
| Pinzette/ Tweezers | 11785 | 14-257 | I | 6 |
| Klemme, sonstige/ Clamps, Other | 34961 | 15-212 | I | 6 |
| Zange, sonstige/ Forceps, Other | 32842 | 15-221 | I | 6 |
| Haken, sonstige/ Hooks, Other | 35105 | 15-225 | I | 6 |
| Nadel, sonstige/ Needles, Other | 12729 | 15-234 | I | 6 |
| Säge, sonstige/ Saws, Other | 34821 | 15-244 | I | 6 |
| Schere, sonstige/ Scissors, Other | 40251 | 15-245 | I | 6 |
| | | | I | 1 |
| Standgefäß/ Jars | 13730 | 15-586 | I | 1 |
| Mikrochirurgieinstrument/ Microsurgical Instruments, | 12726 | 15-621 | I | 6 |
| Hohlmeißelzange, Bandscheibe/ Rongeurs, Intervertebral Disk | 35541 | 15-669 | I | 6 |
| Zange, dental/ Forceps, Dental | 15710 | 15-710 | I | 6 |
| Schraube/ Screws | 16055 | 16-055 | I | 6 |
| Hülse/ Sleeves | 13384 | 16-146 | I | 6 |
| Gipssäge, elektrisch/ Cast Cutters, Electric | 16340 | 16-340 | I | 13 |
| Tasterzirkel, sonstige/ Calipers, Other | 35788 | 16-417 | I | 6 |
| Zange, Niere/ Forceps, Kidney | 16519 | 16-519 | I | 6 |
| Objektträgerhalter/ Slide Holders, | 16926 | 16-926 | I | 1 |
| Extraktor, Fischhaken/ Extractors, Fishhook | 17938 | 17-938 | I | 1 |
| Handstück, chirurgisch/ Handpieces, Surgical | 17949 | 17-949 | I | 1 |
| Handstück/ Handpiece | 32868 | 17-953 | I | 1 |
| Knochenmühle / Bone mills | 18129 | 18-129 | I | 1 |

Dürbheim: 01.04.2021

Thomas Kupferschmid
Verantwortliche Person nach Artikel 15 MDR
Responsible person according to Article 15 MDR

(Name, Funktion / Name, Function)

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