

# EU - Konformitätserklärung

## EU - Declaration of conformity



GmbH & Co. KG  
Turnstr. 31  
75228 Ispringen  
Germany  
SRN: DE-MF-000006299

Hiermit erklären wir in alleiniger Verantwortung, dass die in der Anlage gelisteten Produkte der  
*We hereby declare under our sole responsibility, that the products listed in the attachment, belonging to*

<b>Produktgruppe</b> <i>Product group</i>	<b>Dentallegierungen und Titan für die Prothetik</b> <i>Dental Alloys and Titanium for Prosthetics</i>
<b>Produktgruppenr.</b> <i>Product group no.</i>	<b>10</b> <i>10</i>
<b>MP – Risikoklasse</b> <i>MD - risk class</i>	<b>IIa</b> <i>IIa</i>
<b>Angewandte gemeinsame Spezifikation/en</b> <i>Applied common specification/s</i>	<b>Nicht verfügbar</b> <i>Not available</i>

alle anwendbaren Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte einschließlich der Grundlegenden Sicherheits- und Leistungsanforderungen gemäß Anhang I und (sofern verfügbar) der gemeinsamen Spezifikationen erfüllen. Die Technische Dokumentation entspricht Anhang II und III der Verordnung. Zur Sicherstellung der Einhaltung der Bestimmungen dieser Verordnung, wenden wir ein Qualitätsmanagementsystem gemäß den Anforderungen der (EU) 2017/745 an, welches nach DIN EN ISO 13485 zertifiziert ist.  
*fulfills all applicable requirements of the Regulation (EU) 2017/745 including the General Safety and Performance Requirements according to Annex I and (if available) the above mentioned common specifications. The technical documentation meets the requirements set out in Annex II and III of the Regulation. To ensure compliance with relevant provisions of this Regulation, we apply a quality management system according to the requirements of the (EU) 2017/745, which is certified according to DIN EN ISO 13485.*

<b>Angewandtes Konformitätsbewertungsverfahren</b> <i>Applied conformity assessment procedure</i>	<b>Anhang IX (I) Verordnung (EU) 2017/745 über Medizinprodukte</b> <i>Annex IX (I) Regulation (EU) 2017/745 on medical devices</i>
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<b>Beteiligte Benannte Stelle</b> <i>Involved Notified Body</i>	<b>Notified Body 0483</b> mdc medical device certification GmbH Kriegerstraße 6 70191 Stuttgart, Germany
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<b>EU- Qualitätsmanagementbescheinigung Nr.</b> <i>EU- quality management system certificate no.</i>	<b>D1002600044</b>	<b>Gültig bis</b> <i>valid until</i>	<b>2028-02-02</b>
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Die vorstehende Konformitätserklärung ist gültig bis **2028-02-02**  
*Aforementioned declaration of conformity is valid until*

Ispringen, 2023-08-30

**Ausstellungsort und -datum**  
*Place and date of issue*

  
Dr. Alexander Matz  
Leiter Entwicklung Werkstoffe und Chemie  
*Head of Development Materials and Chemistry*

  
Eberhard Frey  
Qualitätsmanagementbeauftragter  
*Quality Management Representative*

  
Dr. Christoph Schippers  
Person responsible for regulatory compliance

<b>Zweckbestimmung: Dentallegierungen zur Herstellung von Zahnersatz</b>		
<i>Intended purpose: Dental alloys for the production of dental restorations</i>		
<b>REF</b>	<b>product name / trade name</b>	<b>Basic-UDI-DI</b>
100-001-00	remanium® G-soft, casting alloy	++J01110502003350XXXXXXFP
100-100-50	Tritan Ti1, 18 g	++J01110503001350XXXXXXF6
100-101-50	Tritan Ti1, 22 g	++J01110503001350XXXXXXF6
100-102-50	Tritan Ti1, 31 g	++J01110503001350XXXXXXF6
100-103-50	Tritan Ti1, 36 g	++J01110503001350XXXXXXF6
100-105-50	Tritan Ti1, 40 g	++J01110503001350XXXXXXF6
100-107-00	rematitan® M Ti4	++J01110503001350XXXXXXF6
100-145-00	rematitan® powder, 15-45 µm	++J01110503003350XXXXXXGY
100-202-10	rematitan® blank Ti2, 10 mm	++J01110503003350XXXXXXGY
100-202-12	rematitan® blank Ti2, 12 mm	++J01110503003350XXXXXXGY
100-202-15	rematitan® blank Ti2, 15 mm	++J01110503003350XXXXXXGY
100-202-20	rematitan® blank Ti2, 20 mm	++J01110503003350XXXXXXGY
100-205-10	rematitan® blank Ti5, 10 mm	++J01110503003350XXXXXXGY
100-205-12	rematitan® blank Ti5, 12 mm	++J01110503003350XXXXXXGY
100-205-15	rematitan® blank Ti5, 15 mm	++J01110503003350XXXXXXGY
100-205-20	rematitan® blank Ti5, 20 mm	++J01110503003350XXXXXXGY
100-205-25	rematitan® blank Ti5, 25 mm	++J01110503003350XXXXXXGY
100-205-30	rematitan® blank Ti5, 30 mm	++J01110503003350XXXXXXGY
102-001-10	remanium® GM 380+, cast partial denture alloy	++J01110501003350XXXXXXEE
102-005-10	remanium® GM 380+, cast partial denture alloy	++J01110501003350XXXXXXEE
102-100-10	remanium® GM 700+, cast partial denture alloy	++J01110501003350XXXXXXEE
102-200-10	remanium® GM 800+, cast partial denture alloy	++J01110501003350XXXXXXEE
102-205-10	remanium® GM 800+, cast partial denture alloy	++J01110501003350XXXXXXEE
102-250-00	remanium® GM 900, cast partial denture alloy	++J01110501003350XXXXXXEE
102-255-50	remanium® GM 900, cast partial denture alloy	++J01110501003350XXXXXXEE
102-280-00	remanium® GM 280, cast partial denture alloy	++J01110501003350XXXXXXEE
102-280-10	remanium® GM 280, cast partial denture alloy	++J01110501003350XXXXXXEE
102-401-05	remanium® CSe, bonding alloy	++J01110502003350XXXXXXFP
102-403-05	remanium® CSe, bonding alloy	++J01110502003350XXXXXXFP
102-600-01	remanium® 2001, bonding alloy	++J01110501003350XXXXXXEE
102-600-02	remanium® 2001, bonding alloy	++J01110501003350XXXXXXEE
102-600-10	remanium® 2000+, bonding alloy	++J01110501003350XXXXXXEE
102-601-10	remanium® 2000+, bonding alloy	++J01110501003350XXXXXXEE
102-602-10	remanium® 2000+, bonding alloy	++J01110501003350XXXXXXEE
102-620-00	remanium® star, bonding alloy	++J01110501003350XXXXXXEE
102-620-70	remanium® star powder, 10-30 µm	++J01110501003350XXXXXXEE
102-621-00	remanium® star, bonding alloy	++J01110501003350XXXXXXEE
102-622-00	remanium® star, bonding alloy	++J01110501003350XXXXXXEE
102-630-00	remanium® segura, bonding alloy	++J01110501003350XXXXXXEE
102-631-00	remanium® segura, bonding alloy	++J01110501003350XXXXXXEE
102-632-00	remanium® segura, bonding alloy	++J01110501003350XXXXXXEE
102-750-01	remanium® star MD II blank, 8 mm	++J01110501003350XXXXXXEE
102-751-01	remanium® star MD II blank, 10 mm	++J01110501003350XXXXXXEE
102-752-01	remanium® star MD II blank, 12 mm	++J01110501003350XXXXXXEE
102-753-01	remanium® star MD II blank, 13.5 mm	++J01110501003350XXXXXXEE
102-754-01	remanium® star MD II blank, 15 mm	++J01110501003350XXXXXXEE
102-755-01	remanium® star MD II blank, 18 mm	++J01110501003350XXXXXXEE
102-756-01	remanium® star MD II blank, 20 mm	++J01110501003350XXXXXXEE
102-757-01	remanium® star MD II blank, 25 mm	++J01110501003350XXXXXXEE



<b>Zweckbestimmung: Fugematerialien zur Herstellung von Zahnersatz</b>		
<i>Intended purpose: Joining materials for the production of dental restorations</i>		
<b>REF</b>	<b>product name / trade name</b>	<b>Basic-UDI-DI</b>
102-302-00	NiCr-Sold 1	++J01110502003351XXXXXXG8
102-306-00	CoCrMo-Sold 1	++J01110501003351XXXXXXEX
528-039-50	rematitan® wire on coil Ti, round, ø 0.4 mm	++J01110503001351XXXXXXFP
528-040-50	rematitan® wire on coil Ti, round, ø 0.7 mm	++J01110503001351XXXXXXFP
528-041-00	rematitan® straight wire Ti, round, ø 1.0 mm	++J01110503001351XXXXXXFP
528-042-00	rematitan® straight wire Ti, round, ø 1.2 mm	++J01110503001351XXXXXXFP
528-043-00	rematitan® straight wire Ti, rolled, 0.5 x 1.5 mm	++J01110503001351XXXXXXFP
528-050-00	rematitan® straight wire Ti, round, ø 1.5 mm	++J01110503001351XXXXXXFP
528-200-10	CoCr welding wire, ø 0.50 mm	++J01110501001351XXXXXXD5
528-210-10	CoCr welding wire, ø 0.35 mm	++J01110501001351XXXXXXD5
528-215-10	CoCr welding wire, ø 0.25 mm	++J01110501001351XXXXXXD5
528-220-00	NiCr welding wire, ø 0,50 mm	++J01110502001351XXXXXXEE