

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

Produktgruppe <i>Product group</i>	Drähte, Drahtelemente und Bögen <i>Wires, wire elements and arches</i>
Produktgruppennr. <i>Product group no.</i>	4 <i>4</i>
MP – Risikoklasse <i>MD - risk class</i>	I <i>I</i>
Angewandte gemeinsame Spezifikation/en <i>Applied common specification/s</i>	Nicht verfügbar <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.

Angewandtes Konformitätsbewertungsverfahren <i>Applied conformity assessment procedure</i>	Artikel 52 Abschnitt 7 Verordnung (EU) 2017/745 über Medizinprodukte <i>Article 52 section 7 Regulation (EU) 2017/745 on medical devices</i>
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DIN EN ISO 13485 Zertifikat Nr. <i>DIN EN ISO 13485 certificate no.</i>	D1002600039	Gültig bis <i>valid until</i>	2024-12-03
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Die vorstehende Konformitätserklärung ist gültig bis <i>Aforementioned declaration of conformity is valid until</i>	2024-12-03
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Ispringen, 2023-02-27

Ausstellungsort und -datum
Place and date of issue


Thomas Braun
Leiter Entwicklung Orthodontie
Head of Orthodontics Development


Eberhard Frey
Qualitätsmanagementbeauftragter
Quality Management Representative


Dr. Christoph Schippers
Person responsible for regulatory compliance

Zweckbestimmung <i>intended purpose</i>	Drahteile für KFO-Apparaturen <i>Wire elements for orthodontic appliances</i>	
REF	product name / trade name	Basic-UDI-DI
607-202-00	Guide pin acc. to Hinz, round 1.50 mm / 59	++J01104104001158XXXXXXJ6
607-202-30	Guide pin acc. to Hinz, round 1.50 mm / 59	++J01104104001158XXXXXXJ6
607-204-00	Guide pin acc. to G. Müller®	++J01104104001158XXXXXXJ6
607-204-30	Guide pin acc. to G. Müller®	++J01104104001158XXXXXXJ6
620-107-00	remanium® ball retainer clasp, round 0.70 mm / 28	++J01104104001158XXXXXXJ6
620-108-00	remanium® ball retainer clasp, round 0.80 mm / 31	++J01104104001158XXXXXXJ6
620-109-00	remanium® ball retainer clasp, round 0.90 mm / 36	++J01104104001158XXXXXXJ6
620-110-00	remanium® ball retainer clasp, round 1.00 mm / 39	++J01104104001158XXXXXXJ6
620-207-02	Noninium® ball retainer clasp, round 0.70 mm / 28	++J01104104001158XXXXXXJ6
620-208-02	Noninium® ball retainer clasp, round 0.80 mm / 32	++J01104104001158XXXXXXJ6
620-209-02	Noninium® ball retainer clasp, round 0.90 mm / 36	++J01104104001158XXXXXXJ6
620-708-00	remanium® arrow-head clasp, round 0.80 mm / 31	++J01104104001158XXXXXXJ6
621-028-01	Noninium® standard labial arch, length 28 mm	++J01104104001158XXXXXXJ6
621-031-01	Noninium® standard labial arch, length 31 mm	++J01104104001158XXXXXXJ6
621-034-01	Noninium® standard labial arch, length 34 mm	++J01104104001158XXXXXXJ6
621-037-01	Noninium® standard labial arch, length 37 mm	++J01104104001158XXXXXXJ6
621-040-01	Noninium® standard labial arch, length 40 mm	++J01104104001158XXXXXXJ6
621-043-01	Noninium® standard labial arch, length 43 mm	++J01104104001158XXXXXXJ6
621-046-01	Noninium® standard labial arch, length 46 mm	++J01104104001158XXXXXXJ6
621-200-01	Noninium® eyelet clasp, round 0.70 mm / 28	++J01104104001158XXXXXXJ6
621-300-01	Noninium® triangular clasp, round 0.70 mm / 28	++J01104104001158XXXXXXJ6
621-404-01	Noninium® Adams clasp, length 7 mm	++J01104104001158XXXXXXJ6
621-405-01	Noninium® Adams clasp, length 8 mm	++J01104104001158XXXXXXJ6
621-406-01	Noninium® Adams clasp, length 9 mm	++J01104104001158XXXXXXJ6
621-407-01	Noninium® Adams clasp, length 10 mm	++J01104104001158XXXXXXJ6
621-408-01	Noninium® Adams clasp, length 11 mm	++J01104104001158XXXXXXJ6
621-409-01	Noninium® Adams clasp, length 12 mm	++J01104104001158XXXXXXJ6
621-500-01	Noninium® Adams clasps, assortment	++J01104104001158XXXXXXJ6

Zweckbestimmung <i>intended purpose</i>	Drahteile für Prothesen <i>Wire elements for dentures</i>	
REF	product name / trade name	Basic-UDI-DI
309-006-10	Wapo bar, anatomical, normal, length 6 cm	++J01104104001156XXXXXXH4
309-007-10	Wapo bar, anatomical, normal, length 7 cm	++J01104104001156XXXXXXH4
309-008-10	Wapo bar, anatomical, normal, length 8 cm	++J01104104001156XXXXXXH4
311-306-30	Lingual bar, rectangular 3.0 mm x 1.5 mm, length 6 cm	++J01104104001156XXXXXXH4
311-307-30	Lingual bar, rectangular 3.0 mm x 1.5 mm, length 7 cm	++J01104104001156XXXXXXH4
311-308-30	Lingual bar, rectangular 3.0 mm x 1.5 mm, length 8 cm	++J01104104001156XXXXXXH4
312-106-00	Strengtheners, twisted, rolled flat, rectangular 1.80 mm x 0.80 mm	++J01104104001156XXXXXXH4
312-107-00	Strengtheners, twisted, rolled flat, rectangular 2.40 mm x 0.80 mm	++J01104104001156XXXXXXH4
316-110-00	Wire mesh, fine	++J01104104001156XXXXXXH4
316-210-00	Wire mesh, gold-plated, fine	++J01104104001156XXXXXXH4
317-110-00	Wire mesh, coarse	++J01104104001156XXXXXXH4
317-210-00	Wire mesh, gold-plated, coarse	++J01104104001156XXXXXXH4
318-004-00	Grid strengthener	++J01104104001156XXXXXXH4
318-104-00	Grid strengthener, gold-plated	++J01104104001156XXXXXXH4
320-109-00	Bicusps, 0.90 mm / 36	++J01104104001156XXXXXXH4
320-110-00	Molars, 1.00 mm / 39	++J01104104001156XXXXXXH4