



# KONFORMITÄTSERKLÄRUNG DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY DÉCLARATION DE CONFORMITÉ

**Hersteller:**  
**Produttore:**  
**Manufacturer:**  
**Fabricant:**

**Bionah srl**  
Zona produttiva Molini 8  
I – 39032 Campo Tures  
Tel. +39 0474 370 350  
Fax.+39 0474 370 351  
E-Mail: info@bionah.com  
www.bionah.com

**Produkt und Zubehör:**  
**Prodotto e accessori:**  
**Product and accessories:**  
**Produit et accessoires:**

**BionMet CC / T2 / T4 / T5**  
Titan / CoCr Material zur Realisierung von Zahnersatz  
Materiale in titanio / CoCr per la realizzazione di protesi dentali  
Titanium / CoCr material for the manufacture of dental prothesis  
Titane / CoCr matériau pour la fabrication de prothèse dentaire

**Erklärung:**  
**Dichiarazione:**  
**Declaration:**  
**Déclaration:**

In alleiniger Verantwortung erklären wir, dass die oben angeführten Medizinprodukte der Klasse IIa laut Anhang IX, Regel 5 der Richtlinie 93/42/EWG und 2007/47/EWG allen Anforderungen der Medizinprodukte-Richtlinien 93/42/EWG und 2007/47/EWG, als auch der Norm ISO 5832 entsprechen.  
Konformitätsbewertungsverfahren gemäß Anhang II (vollständiges Qualitätssicherungssystem) ohne Nummer 4.

Dichiariamo sotto nostra responsabilità, che i dispositivi medici della classe IIa secondo l'allegato IX, regola 5 della direttiva 93/42/CEE e 2007/47/CEE soddisfano tutte le disposizioni delle direttive 93/42/CEE, 2007/47/CEE e della norma ISO 5832 che lo riguardano.  
Procedimento di valutazione della conformità secondo l'allegato II (sistema completo di garanzia di qualità) senza numero 4.

Herewith we declare under sole responsibility that the medical devices listed above of class IIa according to annex IX, rule 5 of direct 93/42/EEC and 2007/47/EEC meets all the provisions of the directive 93/42/EEC, 2007/47/EEC and the standard ISO 5832 which apply to it.  
Conformity assessment procedure according to annex II (Full quality assurance system) without number 4.

Nous déclarons sous notre seule responsabilité que les dispositifs médicaux énumérés ci-dessus de la classe Iia, règle 5 conformément à l'annexe IX de 93/42/CEE et 2007/47/CEE directe répondent à toutes les dispositions de la directive 93/42/CEE, 2007/47/CEE et ISO 5832 qui lui sont applicables.  
Procédure d'évaluation de la conformité conformément à l'annexe II (Système complet d'assurance de la qualité) sans numéro 4.

**Benannte Stelle:**  
**Organismo notificato:**  
**Notified Body:**  
**Organisme notifié:**

**TÜV Rheinland Italia S.r.l.**  
Via Mattei, 3  
I-Pogliano Milanese  
T +39 02 939 6871  
F +39 02 939 68723



**Gültigkeit:**  
**Validità:**  
**Validity:**  
**Validité:**

Diese Konformitätserklärung ist bis zum 31.12.2018 gültig.  
Questa dichiarazione di conformità è valida fino al 31.12.2018.  
This declaration of conformity is valid until 31.12.2018.  
Cette déclaration de conformité est valable jusqu'au 31.12.2018.

**Ort und Datum - Luogo e data:**  
**Place and date - Date et lieu:**

Campo Tures, 15.11.2017

**Direktor - Direttore:**  
**Director - Directeur:**

Name - Nome - Name - Nom: Pfeifhofer Paul  
Unterschrift - Firma - Signature - Signature:



**ANHANG KONFORMITÄTSERKLÄRUNG  
APPENDICE DICHIARAZIONE DI CONFORMITÀ  
APPENDIX DECLARATION OF CONFORMITY  
ANNEXE DÉCLARATION DE CONFORMITÉ**

**Produkt:  
Prodotto:  
Product:  
Produit:**

**BionMet CC / T2 / T4 / T5**

**Artikelnummer:  
Codici d'articolo:  
Item no.:  
Numéro d'article:**

**BionMET CrCo**

Artikelcode	Bezeichnung
BTC0180M	BionMET CCM 98/12
BTC0190M	BionMET CCM 98/14
BTC0200M	BionMET CCM 98/16
BTC0210M	BionMET CCM 98/18
BTC0220M	BionMET CCM 98/20
BTC0230M	BionMET CCM 98/22
BTC0240W	BionMET CCW 98/10
BTC0250W	BionMET CCW 98/12 S
BTC0260W	BionMET CCW 98/14 S
BTC0270W	BionMET CCW 98/16 S
BTC0280W	BionMET CCW 98/18 S
BTC0290W	BionMET CCW 98/20 S
BTC0300W	BionMET CCW 98/22 S
BTC0421W	BionMET CCW 98/26 S
BTC0431W	BionMET CCW 98/30 S
BTC0500Z	BionMET CCZ 95/10
BTC0510Z	BionMET CCZ 95/12
BTC0520Z	BionMET CCZ 95/14
BTC0530Z	BionMET CCZ 95/16
BTC0540Z	BionMET CCZ 95/18
BTC0550Z	BionMET CCZ 95/20
BTC0560Z	BionMET CCZ 95/22
BTC0570Z	BionMET CCZ 95/25
BTC0590Z	BionMET CCZ 95/30

**BionMET Titan Gr4**

Artikelcode	Bezeichnung
BTD0180M	BionMET T4M 98/12
BTD0190M	BionMET T4M 98/14
BTD0200M	BionMET T4M 98/16
BTD0210M	BionMET T4M 98/18
BTD0220M	BionMET T4M 98/20
BTD0230M	BionMET T4M 98/22
BTD0240W	BionMET T4W 98/10
BTD0250W	BionMET T4W 98/12 S
BTD0260W	BionMET T4W 98/14 S
BTD0270W	BionMET T4W 98/16 S
BTD0280W	BionMET T4W 98/18 S
BTD0290W	BionMET T4W 98/20 S
BTD0300W	BionMET T4W 98/22 S
BTD0421W	BionMET T4W 98/26 S

**BionMET Titan Gr2**

Artikelcode	Bezeichnung
BTB0180M	BionMET T2M 98/12
BTB0190M	BionMET T2M 98/14
BTB0200M	BionMET T2M 98/16
BTB0210M	BionMET T2M 98/18
BTB0220M	BionMET T2M 98/20
BTB0230M	BionMET T2M 98/22
BTB0240W	BionMET T2W 98/10
BTB0250W	BionMET T2W 98/12 S
BTB0260W	BionMET T2W 98/14 S
BTB0270W	BionMET T2W 98/16 S
BTB0280W	BionMET T2W 98/18 S
BTB0290W	BionMET T2W 98/20 S
BTB0300W	BionMET T2W 98/22 S
BTB0421W	BionMET T2W 98/26 S
BTB0431W	BionMET T2W 98/30 S
BTB0500Z	BionMET T2Z 95/10
BTB0510Z	BionMET T2Z 95/12
BTB0520Z	BionMET T2Z 95/14
BTB0530Z	BionMET T2Z 95/16
BTB0540Z	BionMET T2Z 95/18
BTB0550Z	BionMET T2Z 95/20
BTB0560Z	BionMET T2Z 95/22
BTB0570Z	BionMET T2Z 95/25
BTB0590Z	BionMET T2Z 95/30

**BionMET Titan Gr5**

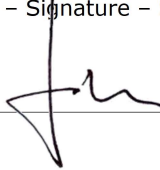
Artikelcode	Bezeichnung
BTE0180M	BionMET T5M 98/12
BTE0190M	BionMET T5M 98/14
BTE0200M	BionMET T5M 98/16
BTE0210M	BionMET T5M 98/18
BTE0220M	BionMET T5M 98/20
BTE0230M	BionMET T5M 98/22
BTE0240W	BionMET T5W 98/10
BTE0250W	BionMET T5W 98/12 S
BTE0260W	BionMET T5W 98/14 S
BTE0270W	BionMET T5W 98/16 S
BTE0280W	BionMET T5W 98/18 S
BTE0290W	BionMET T5W 98/20 S
BTE0300W	BionMET T5W 98/22 S
BTE0421W	BionMET T5W 98/26 S

BTD0431W	BionMET T4W 98/30 S
BTD0500Z	BionMET T4Z 95/10
BTD0510Z	BionMET T4Z 95/12
BTD0520Z	BionMET T4Z 95/14
BTD0530Z	BionMET T4Z 95/16
BTD0540Z	BionMET T4Z 95/18
BTD0550Z	BionMET T4Z 95/20
BTD0560Z	BionMET T4Z 95/22
BTD0570Z	BionMET T4Z 95/25
BTD0590Z	BionMET T4Z 95/30

BTE0431W	BionMET T5W 98/30 S
BTE0500Z	BionMET T5Z 95/10
BTE0510Z	BionMET T5Z 95/12
BTE0520Z	BionMET T5Z 95/14
BTE0530Z	BionMET T5Z 95/16
BTE0540Z	BionMET T5Z 95/18
BTE0550Z	BionMET T5Z 95/20
BTE0560Z	BionMET T5Z 95/22
BTE0570Z	BionMET T5Z 95/25
BTE0590Z	BionMET T5Z 95/30

**Ort und Datum - Luogo e data:** Campo Tures, 15.11.2017  
**Place and date - Date et lieu:**

**Direktor - Direttore:** Name - Nome - Name - Nom: Pfeifhofer Paul  
**Director - Directeur:** Unterschrift - Firma - Signature - Signature:




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