

KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

gemäß Anhang IX der Verordnung (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Hiermit erklären wir in alleiniger Verantwortung, dass die unten aufgeführten Produkte die relevanten allgemeinen Sicherheits- und Leistungsanforderungen gemäß der **Verordnung (EU) 2017/745** über Medizinprodukte erfüllen und mit folgenden Anforderungen konform sind

- der Liste der angewandten Normen
- Gemeinsame Spezifikationen: n/a
- Weitere Regularien: n/a

Diese Konformitätserklärung ist bis zum Ablauf des Zertifikates der Verordnung (EU) 2017/745 über Medizinprodukte (Registrierungsnummer: HZ 1123799-1) und nur zusammen mit den zugehörigen Chargenfreigabedokumenten gültig.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Hersteller <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Deutschland /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| Einmalige Registrierungsnummer <i>Single Registration Number (SRN):</i> | DE-MF-000005414 | |
| Produktfamilie <i>Name of product family:</i> | Laserschweißdraht <i>Wire for laser welding</i> | |
| Produktname und REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Zweckbestimmung <i>Intended purpose:</i> | Kobalt-Basis-Laserdrähte sind Füllstoffe, bestimmt zum Schweißen von dentalen Restaurationen wie Kronen, Brücken, metallkeramischen Zahnersatz sowie Modellguss. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Produktklassifizierung <i>Product class:</i> | Klasse IIa <i>Class IIa</i> | |
| Basis UDI-DI <i>Basic UDI-DI:</i> | ++EBGOCobalt-laserSR | |
| Benannte Stelle <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Deutschland | |

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| | <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| CE-Kennzeichen <i>Marked</i> | CE 0197 |

Andere anwendbaren EU-Sprachen sind in den folgenden Anhängen zu finden.
Other applicable EU-languages can be found in the following Annex.

Bremen, 12.05.2026

Ort, Datum
Place, Date



Steffen Böhm
Managing Director (CPO)



Dr. Ulrich Abend
Person Responsible for Regulatory
Compliance – Technical Documentation

DECLARACIÓN DE CONFORMIDAD DECLARATION OF CONFORMITY

según el anexo IX, Reglamento (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Por la presente declaramos, bajo nuestra única responsabilidad, que los productos que se detallan a continuación cumplen con los requisitos generales de seguridad y rendimiento relevantes según lo establecido del **Reglamento (UE) 2017/745 sobre los productos sanitarios**, y guardan conformidad con

- la lista de normas aplicadas
- especificaciones comunes: n/a
- reglamentos: n/a

Esta declaración de conformidad tiene validez hasta la fecha de vencimiento del certificado REGLAMENTO (UE) 2017/745 sobre los productos sanitarios (número de registro: HZ 1123799-1); y únicamente en combinación con el documento correspondiente de aprobación del lote.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Fabricante <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Alemania /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| número de registro único <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Familia de productos <i>Name of product family</i> | Alambre para soldadura con láser <i>Wire for laser welding</i> | |
| nombre del producto y REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Finalidad prevista <i>Intended purpose</i> | Los alambres para soldadura con láser a base de cobalto son materiales de relleno y están previstos para la soldadura directa de restauraciones dentales como coronas, puentes, prótesis de metalo-cerámica y colado sobre modelo. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Clasificación del producto <i>Product class</i> | Clase IIa <i>Class IIa</i> | |
| UDI-DI básico <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| organismo notificado <i>Notified Body</i> | TUV Rheinland LGA Products GmbH Tillystrasse 2 | |

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| | 90431 Núremberg Alemania <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| mercado CE <i>Marked</i> | CE 0197 |

DÉCLARATION DE CONFOMITÉ DECLARATION OF CONFORMITY

conformément à l'annexe IX, règlement (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Nous déclarons par la présente, sous notre seule responsabilité, que les dispositifs listés ci-après satisfont aux exigences générales pertinentes en matière de sécurité et de performances conformément à du **Règlement (UE) 2017/745 relatif aux dispositifs médicaux** et sont conformes aux

- normes appliquées listées,
- spécifications communes : n/a
- règlements : n/a

Cette déclaration de conformité est valable jusqu'à expiration du Certificat RÈGLEMENT (EU) 2017/745 relatif aux dispositifs médicaux (n° d'enregistrement: HZ 1123799-1) et uniquement avec le document correspondant de libération du lot.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Fabricant <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Allemagne /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| numéro d'enregistrement unique <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Famille de Produits <i>Name of product family</i> | Fil pour soudure au laser <i>Wire for laser welding</i> | |
| nom du produit et REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Destination <i>Intended purpose</i> | les fils laser à base de cobalt sont des charges destinées à la soudure de restaurations dentaires telles que les couronnes, les bridges, les prothèses dentaires céramo-métalliques ainsi que les châssis. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Classe de produit <i>Product class</i> | Classe IIa <i>Class IIa</i> | |
| IUD-ID de base <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |

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| Organisme notifié <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Allemagne <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| CE-marque <i>Marked</i> | CE 0197 |

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

secondo dall'allegato IX, Regolamento (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Con la presente dichiariamo, sotto la nostra esclusiva responsabilità, che i dispositivi elencati di seguito rispettano i pertinenti requisiti generali di sicurezza e prestazione come previsto del **Regolamento (UE) 2017/745 relativo ai Dispositivi Medici** e sono conformi

- all'elenco delle norme applicate
- alle specifiche comuni: n/a
- ai regolamenti: n/a

La presente dichiarazione di conformità è valida fino alla scadenza del Certificato REGOLAMENTO (UE) 2017/745 relativo ai Dispositivi Medici (Numero di Registrazione: HZ 1123799-1) e soltanto in combinazione con il relativo certificato di rilascio del lotto.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Fabbricante <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Germania /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| numero di registrazione unico <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Famiglia di prodotti <i>Name of product family</i> | Filo per saldatura laser <i>Wire for laser welding</i> | |
| nome del prodotto e REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Destinazione d'uso <i>Intended purpose</i> | i fili laser a base di cobalto sono riempitivi indicati per la saldatura di restauri dentali come corone, ponti, protesi dentali in metallo-ceramica e scheletrati. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| classificazione del prodotto <i>Product class</i> | Classe IIa <i>Class IIa</i> | |
| UDI-DI di base <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| organismo notificato | TÜV Rheinland LGA Products GmbH | |

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| <i>Notified Body</i> | Tillystrasse 2 90431 Norimberga Germania <i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i> |
| marchio CE <i>Marked</i> | CE 0197 |

ATBILSTĪBAS DEKLARĀCIJAS DECLARATION OF CONFORMITY

Saskaņā ar IX pielikumā, regula (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Ar šo mēs, uzņemoties pilnu atbildību, deklarējam, ka iepriekš minētie izstrādājumi atbilst attiecīgajām vispārējām drošuma un veiktspējas prasībām saskaņā ar **Regulas (ES) 2017/745 par medicīnas ierīcēm** atbilst

- uzskaitītajiem attiecināmajiem standartiem
- kopīgās specifikācijas: n/a
- regulas: n/a

Šī atbilstības deklarācija ir derīga līdz sertifikāta REGULA (ES) 2017/745 par medicīnas ierīcēm (reģistrācijas Nr.: HZ 1123799-1) derīguma beigām un tikai kopā ar saistītās partijas laidiena dokumentu.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| ražotāji <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Vācija /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| vienotu reģistrācijas numuru (VRN) <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Produktu grupa <i>Name of product family</i> | Lāzermetināšanas stieple <i>Wire for laser welding</i> | |
| Produkta nosaukums un REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Paredzētais nolūks <i>Intended purpose</i> | Kobalta bāzes lāzera stieples ir pildvielas, kas paredzētas tādu dentālo restaurāciju metināšanai kā kroņi, tilti un metālkeramiskie zobu aizvietotāji, kā arī modellējumam. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Produktu klasifikācija <i>Product class</i> | Klase IIa <i>Class IIa</i> | |
| pamata UDI-DI <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| paziņotajai struktūrai | TÜV Rheinland LGA Products GmbH | |

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| <i>Notified Body</i> | Tillystrasse 2 90431 Nirnberga Vācija <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| <i>CE- marķējums Marked</i> | CE 0197 |

ATITIKTIES DEKLARACIJO DECLARATION OF CONFORMITY

Pagal IX priedą IX, reglamentai (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Savo atsakomybe pareiškiame, kad toliau išvardyti gaminiai tenkina atitinkamus bendrosios saugos ir veikimo reikalavimus, numatytus **Medicinos prietaisų reglamento (ES) 2017/745** ir atitinka

- išvardytus taikomus standartus
- bendrosios specifikacijos: n/a
- reglamentai: n/a

Ši atitikties deklaracija galioja iki Medicinos prietaisų reglamente (ES) 2017/745 numatyto sertifikato (registracijos Nr.: HZ 1123799-1) galiojimo pabaigos ir tik kartu su atitinkamos partijos išleidimo dokumentu.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Gamintojų <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Vokietija /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| unikalų registracijos numerį <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| produktų grupė <i>Name of product family</i> | Lazerinio suvirinimo viela <i>Wire for laser welding</i> | |
| produkto pavadinimas ir REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Numatytoji paskirtis <i>Intended purpose</i> | kobalto pagrindu pagamintos lazerio vielos yra užpildai, skirti suvirinti dantų restauracijas, tokias kaip karūnėles, tiltelius, metalo keramikos dantų protezus ir modelių liejinius. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Produkto klasifikacija <i>Product class</i> | Klasė IIa <i>Class IIa</i> | |
| Bazinis UDI-DI <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| įsisteigusi notifikuootoji <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Niurnbergas Vokietija | |

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| | <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| <i>CE ženkl Marked</i> | CE 0197 |

MEGFELELŐSÉGI NYILATKOZATOT DECLARATION OF CONFORMITY

a IX. melléklet szerint, Rendelet (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Ezúton kizárólagos felelősségünk tudatában kijelentjük, hogy az alábbiakban felsorolt termékek betartják **az orvostechnikai eszközökről szóló (EU) 2017/745** mellékletében meghatározott biztonságosságra és teljesítőképességre vonatkozó általános követelményeknek, valamint

- az alkalmazott szabványok listájának
- általános műszaki adatok: n/a
- előírások: n/a

Ez a megfelelőségi nyilatkozat az orvostechnikai eszközökről szóló (EU) 2017/745 RENDELET (regisztrációs szám: HZ 1123799-1) tanúsítványának lejárataig érvényes, és csak a kapcsolódó gyártási tétel felszabadítási dokumentummal együtt.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Gyártó <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Németország/Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| egyedi regisztrációs számot <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Termékcsalád <i>Name of product family</i> | Lézerhegesztő huzal <i>Wire for laser welding</i> | |
| terméknév és REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Rendeltetés <i>Intended purpose</i> | A kobaltbázisú lézerhuzalok olyan töltőanyagok, amelyeket fogászati restaurációk, mint például koronák, hidak, fémkerámia fogpótlások, valamint modellöntvények hegesztésére szántak. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Termékosztályozás <i>Product class</i> | Osztály IIa <i>Class IIa</i> | |
| alapvető UDI-DI-nek <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| bejelentett szervezet | TÜV Rheinland LGA Products GmbH | |

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| <i>Notified Body</i> | Tillystrasse 2 90431 Nürnberg Németország <i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i> |
| <i>CE-jelölés</i> <i>Marked</i> | CE 0197 |

DECLARAÇÃO DE CONFORMIDADE DECLARATION OF CONFORMITY

De acordo com o anexo IX, Regulamentos (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

Declaramos, sob nossa exclusiva responsabilidade, que os produtos abaixo indicados cumprem os requisitos gerais de segurança e desempenho relevantes, de acordo com do **Regulamento (UE) 2017/745 relativo aos Dispositivos Médicos** e estão em conformidade com

- a lista de normas aplicadas
- especificações comuns: n/a
- regulamentos: n/a

Esta declaração de conformidade é válida até ao termo de validade do Certificado REGULAMENTO (UE) 2017/745 relativo aos Dispositivos Médicos (N.º de registo: HZ 1123799-1) e apenas em conjunto com o documento correspondente de libertação do lote.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Fabricante <i>Manufacturer</i> | BEGO Bremer Goldschlögerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Alemanha /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| número único de registo <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| Família de produtos <i>Name of product family</i> | Arame de solda para laser <i>Wire for laser welding</i> | |
| nome de produto y REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Finalidade <i>Intended purpose</i> | Os arames laser à base de cobalto são massas de enchimento, destinados à soldagem de restaurações dentárias como coroas, pontes, próteses dentárias metalocerâmicas e fundição de modelos. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| Classe <i>Product class</i> | Classe IIa <i>Class IIa</i> | |
| UDI-DI básico <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| organismo notificado | TÜV Rheinland LGA Products GmbH | |

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| <i>Notified Body</i> | Tillystrasse 2 90431 Nuremberga Alemanha <i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i> |
| marcação CE <i>Marked</i> | CE 0197 |

IZJAVA O SKLADNOSTI DECLARATION OF CONFORMITY

V skladu s Prilogo IX, Uredbe (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

S tem na izključno lastno odgovornost izjavljamo, da spodaj navedeni izdelki izpolnjujejo veljavne splošne zahteve glede varnosti in učinkovitosti v skladu s **Uredbe (EU) 2017/745 o medicinskih pripomočkih** in so v skladu

- s seznamom uporabljenih standardov
- s skupnimi specifikacijami: n/a
- s predpisi: n/a

Ta izjava o skladnosti je veljavna do poteka certifikata o UREDBI (EU) 2017/745 o medicinskih pripomočkih (registrska št.: HZ 1123799-1) in samo skupaj z ustreznim dokumentom o sprostitvi serije.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Proizvajalcev <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Nemčija /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| enotno registrsko številko <i>Single Registration Number (SRN):</i> | DE-MF-000005414 | |
| družina izdelkov <i>Name of product family</i> | Žica za lasersko varjenje <i>Wire for laser welding</i> | |
| ime izdelka in REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Predvidena uporaba <i>Intended purpose</i> | Laserske žice na osnovi kobalta so polnila, namenjena varjenju zobnih restavracij, kot so krone, mostički, kovinsko-keramične proteze in delne proteze z ulito kovinsko bazo. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| razvrstitev izdelka <i>Product class</i> | Razred IIa <i>Class IIa</i> | |
| Osnovni UDI-DI <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| priglašene organa <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 | |

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| | 90431 Nürnberg Nemčija <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| oznaka CE Marked | CE 0197 |

δήλωση συμμόρφωσης ΕΕ DECLARATION OF CONFORMITY

σύμφωνα με το παράρτημα ΙΧ, ΚΑΝΟΝΙΣΜΟΙ (ΕΥ) 2017/745
according to annex IX, Regulation (EU) 2017/745

Με το παρόν δηλώνουμε με αποκλειστική μας ευθύνη ότι τα προϊόντα που αναφέρονται παρακάτω συμμορφώνονται τις σχετικές γενικές απαιτήσεις ασφάλειας και επιδόσεων σύμφωνα με του **Κανονισμού (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα** και είναι σύμφωνες με

- τον κατάλογο των εφαρμοζόμενων προτύπων
- κοινές προδιαγραφές: n/a
- τους κανονισμούς: n/a

Η παρούσα δήλωση συμμόρφωσης ισχύει μέχρι τη λήξη του Πιστοποιητικού σύμφωνα με τον ΚΑΝΟΝΙΣΜΟ (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα (Αριθ. πρωτοκόλλου: HZ 1123799-1) και μόνο σε συνδυασμό με το σχετικό έγγραφο αποδέσμευσης παρτίδων.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Κατασκευαστές <i>Manufacturer</i> | BEGO Bremer Goldschlãgerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Γερμανία /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| ενιαίο αριθμό καταχώρισης <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| οικογένεια προϊόντων <i>Name of product family</i> | Σύρμα συγκόλλησης λέιζερ <i>Wire for laser welding</i> | |
| όνομα προϊόντος και REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Προβλεπόμενη χρήση <i>Intended purpose</i> | Τα σύρματα λέιζερ βάσης κοβαλτίου αποτελούν πληρωτικά που προορίζονται για την αυτογενή συγκόλληση οδοντικών αποκαταστάσεων, όπως στεφανών, γεφυρών, μεταλλοκεραμικών οδοντικών προσθέσεων, καθώς και χυτών προπλασμάτων. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| ταξινόμηση προϊόντος <i>Product class</i> | Κατηγορία IIa <i>Class IIa</i> | |
| βασικό UDI-DI <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |
| κοινοποιημένο οργανισμό | TÜV Rheinland LGA Products GmbH | |

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| <i>Notified Body</i> | <p>Tillystrasse 2 90431 Νυρεμβέργη Γερμανία</p> <p><i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i></p> |
| σήμανση CE <i>Marked</i> | CE 0197 |

ЕС декларацията за съответствие DECLARATION OF CONFORMITY

съгласно приложение IX, РЕГЛАМЕНТИ (EU) 2017/745
according to annex IX, Regulation (EU) 2017/745

С настоящото декларираме под пълна отговорност, че продуктите, изброени по-долу, отговарят на съответните общи изисквания за безопасност и действие съгласно от **Регламент (ЕС) 2017/745 за медицинските изделия** и са в съответствие със

- списъка с прилагани стандарти
- общи спецификации: n/a
- регламенти: n/a

Настоящата декларация за съответствие е валидна до изтичане на срока на валидност на сертификата по РЕГЛАМЕНТ (ЕС) 2017/745 за медицинските изделия (регистрационен номер: HZ 1123799-1) и само заедно със съответния документ за освобождаване на партидата.

*We herewith declare under sole responsibility that the products listed below are in conformity with the relevant general safety and performance requirements according to the **Regulation (EU) 2017/745 on Medical Devices** and is in conformity with*

- *the list of applied standards*
- *Common specifications: n/a*
- *Regulations: n/a*

This declaration of conformity is valid until expiration of the Certificate REGULATION (EU) 2017/745 on Medical Devices (Registration No.: HZ 1123799-1) and only together with the related batch release document.

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| Производителит <i>Manufacturer</i> | BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen, Германия /Germany T. +49 421 2028-0 F. +49 421 2028-100 www.bego.com | |
| единен регистрационен номер (EPH) <i>Single Registration Number (SRN)</i> | DE-MF-000005414 | |
| продуктова група <i>Name of product family</i> | Лазерна заваръчна тел Wiroweld се доставя под <i>Wire for laser welding</i> | |
| наименование на продукта и REF <i>Name of products and REF</i> | Wiroweld | 50003, 50005 |
| Предназначение <i>Intended purpose</i> | Лазерните телове на основата на кобалт са пълнители, предназначени за заваряване на дентални възстановявания, като коронки, мостове, металокерамични и моделно лети протези. <i>Cobalt-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges, metal-ceramic restorations as well as partial dentures.</i> | |
| класификация на продукта <i>Product class</i> | Клас IIa <i>Class IIa</i> | |
| Базовият UDI-DI <i>Basic UDI-DI</i> | ++EBGOCobalt-laserSR | |

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| нотифицирания орган <i>Notified Body</i> | TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Нюрнберг Германия <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i> |
| маркировка CE <i>Marked</i> | CE 0197 |