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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.

Hersteller *Manufacturer*	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 *Single Registration Number (SRN):*	DE-MF-000005414
Produktfamilie *Name of product family:*	Edelmetall-Laserdrähte *Noble metal-based laser wires*
Produktname und REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150
Zweckbestimmung *Intended purpose:*	Edelmetall-Laserdrähte sind Füllstoffe, bestimmt zum Schweißen von dentalen Restaurationen wie Kronen, Brücken sowie für metallkeramischen Zahnersatz.

	Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.
Produktklassifizierung *Product class:*	Klasse IIa *Class IIa*
Basis UDI-DI *Basic UDI-DI:*	++EBGONoble-laserCM
Benannte Stelle *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Deutschland *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
CE-Kennzeichen *Marked*	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.

Fabricante *Manufacturer*	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 *Single Registration Number (SRN)*	DE-MF-000005414
Familia de productos *Name of product family*	Alambre para soldadura con láser *Noble metal-based laser wires*
nombre del producto y REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150
Finalidad prevista *Intended purpose*	Los alambres para soldadura con láser de metales nobles son materiales de relleno y están previstos para la soldadura directa de

	restauraciones dentales como coronas, puentes y prótesis de metalo-cerámica. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
Clasificación del producto *Product class*	Clase IIa *Class IIa*
UDI-DI básico *Basic UDI-DI*	++EBGONoble-laserCM
organismo notificado *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Núremberg Alemania *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
marcado CE *Marked*	CE 0197

DÉCLARACION DE CONFOMITÉ
DECLARATION OF CONFORMITY

conformément à l'annexe IX, réglement (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.

Fabricant *Manufacturer*	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 *Single Registration Number (SRN)*	DE-MF-000005414
Famille de Produits *Name of product family*	Alliage dentaire a base de cobalt pour la céramo-métallique *Noble metal-based laser wires*
nom du produit et REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150

Destination *Intended purpose*	Les fils laser à base de métaux précieux sont des charges destinées à la soudure de restaurations dentaires telles que les couronnes, les bridges ainsi que les prothèses dentaires céramo-métalliques. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
Classe de produit *Product class*	Classe IIa *Class IIa*
IUD-ID de base *Basic UDI-DI*	++EBGONoble-laserCM
Organisme notifié *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Allemagne *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
CE-marque *Marked*	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.

Fabbricante *Manufacturer*	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 *Single Registration Number (SRN)*	DE-MF-000005414
Famiglia di prodotti *Name of product family*	Lega dentale a base di cobalto per metallo-ceramica *Noble metal-based laser wires*
nome del prodotto e REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150

Destinazione d'uso *Intended purpose*	i fili laser in metalli preziosi sono riempitivi indicati per la saldatura di restauri dentali come corone, ponti e protesi dentali in metallo-ceramica. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
classificazione del prodotto *Product class*	Classe IIa *Class IIa*
UDI-DI di base *Basic UDI-DI*	++EBGONoble-laserCM
organismo notificato *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga Germania *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
marchio CE *Marked*	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.

ražotāji *Manufacturer*	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) *Single Registration Number (SRN)*	DE-MF-000005414	
Produktu grupa *Name of product family*	Dentāls Co bāzes leģējums metāla keramikai *Noble metal-based laser wires*	
Produkta nosaukums un REF *Name of products and REF*	AuroLloyd® KF-Draht	61153
	BegoCer® G-Draht	61164
	BegoPal® 300-Draht	61165
	BegoStar® ECO-Draht	61171
	Bio PlatinLloyd®-Draht	61161
	Bio PontoStar® -Draht	61157
	Bio PontoStar® XL-Draht	61167
	ECO d'OR-Draht	61170
	PlatinLloyd® 100-Draht	61152
	PlatinLloyd® KF-Draht	61158
	PlatinLloyd® M-Draht	61155
	PontoLloyd® P-Draht	61154
	Pontonorm-Draht	61172
	PontoStar® G-Draht	61150

Paredzētais nolūks *Intended purpose*	Cēlmetāla lāzera stieples ir pildvielas, kas paredzētas tādu dentālo restaurāciju metināšanai kā kroņi, tilti un metālkeramiskie zobu aizvietotāji. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
Produktu klasifikācija *Product class*	Klase IIa *Class IIa*
pamata UDI-DI *Basic UDI-DI*	++EBGONoble-laserCM
paziņotajai struktūrai *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nirnberga Vācija *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
CE- marķējums *Marked*	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.

Gamintojų *Manufacturer*	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
unikalųjį registracijos numerį *Single Registration Number (SRN)*	DE-MF-000005414
produktų grupė *Name of product family*	Lazerinio suvirinimo viela *Noble metal-based laser wires*
produkto pavadinimas ir REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150
Numatytoji paskirtis *Intended purpose*	tauriųjų metalų lazerio vielos yra užpildai, skirti suvirinti dantų restauracijas, tokias kaip karūnėles, tiltelius, taip pat metalo keramikos dantų protezus.

	Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.
Produkto klasifikacija *Product class*	Klasė IIa *Class IIa*
Bazinis UDI-DI *Basic UDI-DI*	++EBGONoble-laserCM
įsisteigusi notifikuotoji *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Niurnbergas Vokietija *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
CE ženklu *Marked*	CE 0197

MEGFELELŐSÉGI NYILATKOZATOT
DECLARATION OF CONFORMITY

a IX. melléklet szerint, Rendeletek (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 lejáratáig 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.

Gyártó *Manufacturer*	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 *Single Registration Number (SRN)*	DE-MF-000005414
Termékcsalád *Name of product family*	Lézerhegesztő huzal *Noble metal-based laser wires*
terméknév és REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150

Rendeltetés *Intended purpose*	A nemesfém lézerhuzalok olyan töltőanyagok, amelyeket fogászati restaurációk, mint például koronák, hidak, valamint fémkerámia fogpótlások hegesztésére szántak. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
Termékosztályozás *Product class*	Osztály IIa *Class IIa*
alapvető UDI-DI-nek *Basic UDI-DI*	++EBGONoble-laserCM
bejelentett szervezet *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Németország *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
CE-jelölés *Marked*	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.

Fabricante *Manufacturer*	BEGO Bremer Goldschlägerei 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 *Single Registration Number (SRN)*	DE-MF-000005414
Família de produtos *Name of product family*	Arame de solda para laser *Noble metal-based laser wires*
nome de produto y REF *Name of products and REF*	

AuroLloyd® KF-Draht	61153
BegoCer® G-Draht	61164
BegoPal® 300-Draht	61165
BegoStar® ECO-Draht	61171
Bio PlatinLloyd®-Draht	61161
Bio PontoStar® -Draht	61157
Bio PontoStar® XL-Draht	61167
ECO d'OR-Draht	61170
PlatinLloyd® 100-Draht	61152
PlatinLloyd® KF-Draht	61158
PlatinLloyd® M-Draht	61155
PontoLloyd® P-Draht	61154
Pontonorm-Draht	61172
PontoStar® G-Draht	61150

Finalidade prevista *Intended purpose*	Os arames laser de metais nobres são massas de enchimento, destinados à soldagem de restaurações dentárias como coroas, pontes e próteses dentárias metalocerâmicas. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
Classe *Product class*	Classe IIa *Class IIa*
UDI-DI básico *Basic UDI-DI*	++EBGONoble-laserCM
organismo notificado *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberga Alemanha *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
marcação CE *Marked*	CE 0197

IZJAVO 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.

Proizvajalcev *Manufacturer*	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 *Single Registration Number (SRN):*	DE-MF-000005414
družina izdelkov *Name of product family*	Žica za lasersko varjenje *Noble metal-based laser wires*
ime izdelka in REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150

Predvidena uporaba *Intended purpose*	Laserske žice iz plemenitih kovin so polnila, namenjena varjenju zobnih restavracij, kot so krone, mostički in kovinsko- keramične proteze. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
razvrstitev izdelka *Product class*	Razred IIa *Class IIa*
Osnovni UDI-DI *Basic UDI-DI*	++EBGONoble-laserCM
priglašenega organa *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Nemčija *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
oznaka CE *Marked*	CE 0197

δήλωση συμμόρφωσης ΕΕ
DECLARATION OF CONFORMITY

σύμφωνα με το παράρτημα IX, ΚΑΝΟΝΙΣΜΟΙ (EU) 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.

Κατασκευαστές *Manufacturer*	BEGO Bremer Goldschlägerei 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 *Single Registration Number (SRN)*	DE-MF-000005414
οικογένεια προϊόντω *Name of product family*	Σύρμα συγκόλλησης λέιζερ *Noble metal-based laser wires*
όνομα προϊόντος και REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150
Προβλεπόμενη χρήση *Intended purpose*	Τα σύρματα λέιζερ ευγενών μετάλλων αποτελούν πληρωτικά που προορίζονται για την αυτογενή συγκόλληση οδοντικών

	αποκαταστάσεων, όπως στεφανών, γεφυρών, καθώς και μεταλλοκεραμικών οδοντικών προσθέσεων. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
ταξινόμηση προϊόντος *Product class*	Κατηγορία IIa *Class IIa*
βασικό UDI-DI *Basic UDI-DI*	++EBGONoble-laserCM
κοινοποιημένο οργανισμό *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Νυρεμβέργη Γερμανία *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
σήμανση CE *Marked*	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: xxx*

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.

Производителит *Manufacturer*	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) *Single Registration Number (SRN)*	DE-MF-000005414
продуктова група *Name of product family*	Лазерна заваръчна тел *Noble metal-based laser wires*
наименование на продукта и REF *Name of products and REF*	AuroLloyd® KF-Draht 61153 BegoCer® G-Draht 61164 BegoPal® 300-Draht 61165 BegoStar® ECO-Draht 61171 Bio PlatinLloyd®-Draht 61161 Bio PontoStar® -Draht 61157 Bio PontoStar® XL-Draht 61167 ECO d'OR-Draht 61170 PlatinLloyd® 100-Draht 61152 PlatinLloyd® KF-Draht 61158 PlatinLloyd® M-Draht 61155 PontoLloyd® P-Draht 61154 Pontonorm-Draht 61172 PontoStar® G-Draht 61150

Предназначение *Intended purpose*	Лазерните телове от благородни метали са пълнители, предназначени за заваряване на дентални възстановявания, като коронки, мостове и металокерамични протези. *Noble metal-based laser wires are filler materials and intended for welding of dental restorations such as crowns, bridges as well as metal- ceramic restorations.*
класификация на продукта *Product class*	Клас IIa *Class IIa*
Базовият UDI-DI *Basic UDI-DI*	++EBGONoble-laserCM
нотифицирания орган *Notified Body*	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Нюрнберг Германия *TÜV Rheinland LGA Products GmbH* *Tillystrasse 2* *90431 Nuremberg* *Germany*
маркировка CE *Marked*	CE 0197