

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 <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>	Lot für Edelmetall-Legierungen <i>Brazing material for noble metal alloys</i>	
Produktname und REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Zweckbestimmung <i>Intended purpose:</i>	Edelmetall-Lötmaterialien sind Füllstoffe, bestimmt zum Löten von dentalen Restaurationen wie Kronen, Brücken sowie für metallkeramischen Zahnersatz. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Produktklassifizierung <i>Product class:</i>	Klasse IIa <i>Class IIa</i>	
Basis UDI-DI <i>Basic UDI-DI:</i>	++EBGONoble-braz-matSH	

de / en

<p>Benannte Stelle <i>Notified Body</i></p>	<p>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Deutschland</p> <p><i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i></p>
<p>CE-Kennzeichen <i>Marked</i></p>	<p>CE 0197</p>

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 <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>	Material de aportación para aleaciones con metales nobles <i>Brazing material for noble metal alloys</i>	
nombre del producto y REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Finalidad prevista <i>Intended purpose</i>	Los materiales de soldadura de metales nobles son materiales de relleno y están previstos para la soldadura indirecta de restauraciones dentales como coronas, puentes y prótesis de metalo-cerámica. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Clasificación del producto <i>Product class</i>	Clase IIa <i>Class IIa</i>	
UDI-DI básico <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH	

<p>organismo notificado <i>Notified Body</i></p>	<p>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Alemania</p> <p><i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i></p>
<p>marcado CE <i>Marked</i></p>	<p>CE 0197</p>

DÉCLARATION DE CONFORMITÉ 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.

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>	Matériau d'apport pour alliages précieux <i>Brazing material for noble metal alloys</i>	
nom du produit et REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Destination <i>Intended purpose</i>	les produits de brasage à base de métaux précieux sont des charges destinées au brasage de restaurations dentaires telles que les couronnes, les bridges ainsi que les prothèses dentaires céramo-métalliques. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Classe de produit	Classe IIa	

<i>Product class</i>	<i>Class IIa</i>
IUD-ID de base <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
Organisme notifié <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Allemagne TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany
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.

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>	Lot per leghe di metalli preziosi <i>Brazing material for noble metal alloys</i>	
nome del prodotto e REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Destinazione d'uso <i>Intended purpose</i>	i materiali per la brasatura di metalli preziosi sono riempitivi indicati per la brasatura di restauri dentali come corone, ponti e protesi dentali in metallo-ceramica. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
classificazione del prodotto <i>Product class</i>	Classe IIa <i>Class IIa</i>	

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UDI-DI di base <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
organismo notificato <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Norimberga Germania <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg 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.

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>	Lodējamais materiāls cēlmetālu sakausējumiem <i>Brazing material for noble metal alloys</i>	
Produkta nosaukums un REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Paredzētais nolūks <i>Intended purpose</i>	Cēlmetāla lodēšanas materiāli ir pildvielas, kas paredzētas tādu dentālo restaurāciju izgatavošanai kā kroņi, tilti un metālkeramiskie zobu aizvietotāji. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Produktu klasifikācija <i>Product class</i>	Klase IIa <i>Class IIa</i>	

pamata UDI-DI <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
paziņotajai struktūrai <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nirnberga Vācija <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i>
CE- marķējums <i>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.

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>	Lydmetalis tauriųjų metalų lydiniams <i>Brazing material for noble metal alloys</i>	
produkto pavadinimas ir REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Numatytoji paskirtis <i>Intended purpose</i>	tauriųjų metalų litavimo medžiagos yra užpildai, skirti lituoti dantų restauracijas, tokias kaip karūnelės, tilteliusi, taip pat metalo keramikos dantų protezus. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Produkto klasifikacija <i>Product class</i>	Klasė IIa <i>Class IIa</i>	
Bazinis UDI-DI <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH	

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<p>įsisteigusi notifikuotoji <i>Notified Body</i></p>	<p>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Niurnbergas Vokietija</p> <p><i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i></p>
<p>CE ženklų <i>Marked</i></p>	<p>CE 0197</p>

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 orvostechikai 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 orvostechikai 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 <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>	Forrasz nemesfém ötvözetekhez <i>Brazing material for noble metal alloys</i>	
terméknév és REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Rendeltetés <i>Intended purpose</i>	A nemesfém forrasztóanyagok olyan töltőanyagok, amelyeket fogászati restaurációk, mint például koronák, hidak és fémkerámia fogpótlások forrasztására szántak. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Termékosztályozás <i>Product class</i>	Osztály IIa <i>Class IIa</i>	

alapvető UDI-DI-nek <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
bejelentett szervezet <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Németország TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany
CE-jelölés <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.

Fabricante <i>Manufacturer</i>	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 <i>Single Registration Number (SRN)</i>	DE-MF-000005414	
Família de produtos <i>Name of product family</i>	Solda para ligas de metais nobres <i>Brazing material for noble metal alloys</i>	
nome de produto y REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Finalidade <i>Intended purpose</i>	Os materiais de soldadura de metais nobres são massas de enchimento, destinadas à soldadura de restaurações dentárias como coroas, pontes e próteses dentárias metalocerâmicas. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
Classe <i>Product class</i>	Classe IIa <i>Class IIa</i>	

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UDI-DI básico <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
organismo notificado <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberga Alemanha <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg 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.

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>	Spajka za zlitine iz plemenitih kovin <i>Brazing material for noble metal alloys</i>	
ime izdelka in REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Predvidena uporaba <i>Intended purpose</i>	Materiali za spajkanje iz plemenitih kovin so polnila, namenjena spajkanju zobnih restavracij, kot so krone, mostički in kovinsko keramične proteze. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
razvrstitev izdelka <i>Product class</i>	Razred IIa <i>Class IIa</i>	
Osnovni UDI-DI	++EBGONoble-braz-matSH	

<i>Basic UDI-DI</i>	
<i>priglašene organa Notified Body</i>	<i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Nemčija</i> <i>TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany</i>
<i>oznaka CE Marked</i>	CE 0197

δήλωση συμμόρφωσης ΕΕ DECLARATION OF CONFORMITY

σύμφωνα με το παράρτημα IX, 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.

Κατασκευαστές <i>Manufacturer</i>	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 <i>Single Registration Number (SRN)</i>	DE-MF-000005414	
οικογένεια προϊόντων <i>Name of product family</i>	Συγκολλητικό κράμα για κράματα ευγενών μετάλλων <i>Brazing material for noble metal alloys</i>	
όνομα προϊόντος και REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Προβλεπόμενη χρήση <i>Intended purpose</i>	Τα κράματα συγκόλλησης ευγενών μετάλλων αποτελούν πληρωτικά που προορίζονται για την ετερογενή συγκόλληση οδοντικών αποκαταστάσεων, όπως στεφανών, γεφυρών, καθώς και μεταλλοκεραμικών οδοντικών προσθέσεων. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
ταξινόμηση προϊόντος <i>Product class</i>	Κατηγορία IIa <i>Class IIa</i>	

βασικό UDI-DI <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
κοινοποιημένο οργανισμό <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Νυρεμβέργη Γερμανία TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany
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.

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>	Припой за сплави от благородни метали <i>Brazing material for noble metal alloys</i>	
наименование на продукта и REF <i>Name of products and REF</i>	BEGO-Gold-Lot I	61017
	BEGO-Gold-Lot II	61043
	BegoStar®-Lot	61081
	PontoRex®-Lot nach dem Brand	61039
	PontoRex®-Lot vor dem Brand	61038
	PontoStar® G-Lot	61045
Предназначение <i>Intended purpose</i>	Припойните материали от благородни метали са пълнители, предназначени за запояване на дентални възстановявания, като коронки, мостове и металокерамични протези. <i>Noble metal-based brazing materials are filler materials and intended for brazing of dental restorations such as crowns, bridges as well as metal-ceramic restorations.</i>	
класификация на продукта <i>Product class</i>	Клас IIa <i>Class IIa</i>	

Базовият UDI-DI <i>Basic UDI-DI</i>	++EBGONoble-braz-matSH
нотифицирания орган <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Нюрнберг Германия TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg Germany
маркировка CE <i>Marked</i>	CE 0197