

# 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>	Edelmetall-Gusslegierung <i>Noble metal-based casting alloy</i>	
Produktname und REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Zweckbestimmung <i>Intended purpose:</i>	Edelmetall-Gusslegierungen sind bestimmt zur Herstellung von dentalen Restaurationen wie Kronen und Brücken. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Produktklassifizierung <i>Product class:</i>	Klasse IIa <i>Class IIa</i>	
Basis UDI-DI <i>Basic UDI-DI:</i>	++EBGOCasting-alloysEY	
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>	<b>CE 0197</b>

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>	Aleación de fundición de metales nobles <i>Noble metal-based casting alloy</i>	
nombre del producto y REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Finalidad prevista <i>Intended purpose</i>	las aleaciones de fundición de metales nobles están previstas para la elaboración de restauraciones dentales como coronas y puentes. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Clasificación del producto <i>Product class</i>	Clase IIa <i>Class IIa</i>	
UDI-DI básico <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
organismo notificado <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg Alemania	

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

# 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>	Alliage de coulée à base de métaux précieux Noble metal-based casting alloy	
nom du produit et REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Destination <i>Intended purpose</i>	Les alliages de coulée à base de métaux précieux sont destinés à la fabrication de restaurations dentaires telles que les couronnes et les bridges. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Classe de produit <i>Product class</i>	Classe IIa <i>Class IIa</i>	
IUD-ID de base <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	

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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>	<b>CE 0197</b>

## 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>	Lega per colata di metalli preziosi Noble metal-based casting alloy	
nome del prodotto e REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Destinazione d'uso <i>Intended purpose</i>	Le leghe per colata di metalli preziosi sono indicate per la realizzazione di restauri dentali, ad es. corone e ponti. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
classificazione del prodotto <i>Product class</i>	Classe IIa <i>Class IIa</i>	
UDI-DI di base <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
organismo notificato <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2	

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

## 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>	Cēlmetālu lējuma sakausējums Noble metal-based casting alloy	
Produkta nosaukums un REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Paredzētais nolūks <i>Intended purpose</i>	cēlmetālu lējuma sakausējumi paredzēti zobu restaurācijai, kā kroņus un tiltu izgatavošana. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Produktu klasifikācija <i>Product class</i>	Klase IIa <i>Class IIa</i>	
pamata UDI-DI <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
paziņotajai struktūrai <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2	

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

## 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 Goldschlögerei 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>	Tauriojo metalo liejimo lydinys Noble metal-based casting alloy	
produkto pavadinimas ir REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Numatytoji paskirtis <i>Intended purpose</i>	tauriųjų metalų liejimo lydiniai skirti dantų restauracijoms, dantų restauracijoms, tokioms kaip karūnėlės ir tilteliai, gaminti. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Produkto klasifikacija <i>Product class</i>	Klasė IIa <i>Class IIa</i>	
Bazinis UDI-DI <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
įsisteigusi notifikuotoji <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnbergas Vokietija	

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

## 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 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.*

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>	Nemesfém öntött ötvözet Noble metal-based casting alloy	
terméknév és REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Rendeltetés <i>Intended purpose</i>	A nemesfém öntöttötvözeteket fogászati restaurációk, például koronák és hidak gyártására szánják. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Termékosztályozás <i>Product class</i>	Osztály IIa <i>Class IIa</i>	
alapvető UDI-DI-nek <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
bejelentett szervezet <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2	

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

## 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>	Liga de fundição de metal nobre Noble metal-based casting alloy	
nome de produto y REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Finalidade <i>Intended purpose</i>	As ligas de fundição de metais nobres destinam-se ao fabrico de restaurações dentárias como coroas e pontes. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
Classe <i>Product class</i>	Classe IIa <i>Class IIa</i>	
UDI-DI básico <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
organismo notificado <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2	

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

## 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 <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>	Zlitina za litje plemenitih kovin Noble metal-based casting alloy	
ime izdelka in REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Predvidena uporaba <i>Intended purpose</i>	Zlitine za litje plemenitih kovin so namenjene izdelavi zobnih restavracij, kot so krone in mostički. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
razvrstitev izdelka <i>Product class</i>	Razred IIa <i>Class IIa</i>	
Osnovni UDI-DI <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
priglašenega organa <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nürnberg	

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

## 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>	Χυτοκράμα ευγενών μετάλλων Noble metal-based casting alloy	
όνομα προϊόντος και REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Προβλεπόμενη χρήση <i>Intended purpose</i>	τα χυτοκράματα ευγενών μετάλλων προορίζονται για την κατασκευή οδοντικών αποκαταστάσεων, όπως στεφανών και γεφυρών. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
ταξινόμηση προϊόντος <i>Product class</i>	Κατηγορία IIa Class IIa	
βασικό UDI-DI <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
κοινοποιημένο οργανισμό <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Νυρεμβέργη	

el / en

	Γερμανία <i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i>
σήμανση CE <i>Marked</i>	<b>CE 0197</b>

## 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>	Сплав за леене от благородни метали Noble metal-based casting alloy	
наименование на продукта и REF <i>Name of products and REF</i>	AuroLloyd® M	61054
	PlatinLloyd® 100	61020
	PlatinLloyd® M	61009
Предназначение <i>Intended purpose</i>	Сплавите за леене от благородни метали са предназначени за изработка на дентални възстановявания като коронки и мостове. <i>Noble metal-based casting alloys are intended for casting of dental restorations such as crowns and bridges.</i>	
класификация на продукта <i>Product class</i>	Клас IIa <i>Class IIa</i>	
Базовият UDI-DI <i>Basic UDI-DI</i>	++EBGOCasting-alloysEY	
нотифицирания орган <i>Notified Body</i>	TÜV Rheinland LGA Products GmbH Tillystrasse 2	

	90431 Нюрнберг Германия  <i>TÜV Rheinland LGA Products GmbH</i> <i>Tillystrasse 2</i> <i>90431 Nuremberg</i> <i>Germany</i>
маркировка CE <i>Marked</i>	<b>CE 0197</b>