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:*	Permanente Harze *Resins Permanent*	
Produktname und REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Zweckbestimmung *Intended purpose:*	Ein lichthärtender, fließfähiger Kunststoff auf der Basis von Methacrylsäureestern zur Herstellung von definitiven Einzelkronen, Inlays, Onlays und Veneers. *A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.*	
Produktklassifizierung	Klasse IIa	

Product class:	*Class IIa*
Basis UDI-DI *Basic UDI-DI:*	++EBGOResins-permanentFA
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)

Thorsten Palmer
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*	Resinas permanentes *Resins Permanent*	
nombre del producto y REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Finalidad prevista *Intended purpose*	Una resina fluida fotopolimerizable a base de ésteres de ácido meta crílico para la fabricación de coronas individuales permanentes, inlays, onlays y carillas. *A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.*	
Clasificación del producto	Clase IIa	

Product class	*Class IIa*
UDI-DI básico *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Résines permanentes *Resins Permanent*	
nom du produit et REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Destination *Intended purpose*	Une résine fluide photopolymérisable à base d'esters d'acides méthacryliques destinée à la fabrication de couronnes singles permanentes, inlays, onlays et veneers.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
Classe de produit *Product class*	Classe IIa *Class IIa*
IUD-ID de base *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Resine permanenti *Resins Permanent*	
nome del prodotto e REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Destinazione d'uso *Intended purpose*	Una resina fotopolimerizzabile, fluida, a base di esteri di acido meta crilico, per permanenti di corone singole permanenti, inlay, onlay e faccette.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
classificazione del prodotto *Product class*	Classe IIa *Class IIa*
UDI-DI di base *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Sveķi pastāvīgi *Resins Permanent*	
Produkta nosaukums un REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Paredzētais nolūks *Intended purpose*	Gaismas cietējošs, plūstošs sintētiskais materiāls uz metakrilaskābju esteru bāzes, kas paredzēts galīgo atsevišķo kroņu, inleju, onleju un venīru izgatavošanai.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
Produktu klasifikācija *Product class*	Klase IIa *Class IIa*
pamata UDI-DI *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Dervos nuolatinės *Resins Permanent*	
produkto pavadinimas ir REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Numatytoji paskirtis *Intended purpose*	Yra šviesoje kietėjantis, tekus plastikas metakrilo rūgšties esterių pagrindu galutiniams atskiriems vainikėliams, įklotams, už klotams ir laminatėms gaminti. *A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.*	
Produkto klasifikacija	Klasė IIa	

Product class	*Class IIa*
Bazinis UDI-DI *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Gyanták állandó *Resins Permanent*	
terméknév és REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Rendeltetés *Intended purpose*	Végleges egyedi fogkoronák és hidak, inlay-k, onlay-k és veneer-ek előállítása során használatos metakrilsav-észtereken alapuló, fényre keményedő, folyékony műanyag.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
Termékosztályozás *Product class*	Osztály IIa *Class IIa*
alapvető UDI-DI-nek *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Resinas permanentes *Resins Permanent*	
nome de produto y REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Finalidade *Intended purpose*	Um plástico fluido de fotopolimerização à base de ésteres de ácido de metacrílico para a criação de coroas unitárias, enchi mentos, revestimentos e facetas definitivos.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
Classe *Product class*	Classe IIa *Class IIa*
UDI-DI básico *Basic UDI-DI*	++EBGOResins-permanentFA
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*	Smole trajno *Resins Permanent*	
ime izdelka in REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Predvidena uporaba *Intended purpose*	Je tekoča umetna masa na osnovi estra metakrilne kisline, ki se strjuje na svetlobi za izdelavo stalnih enojnih kron, Inlayev, Onlayev in zobnih lusk. *A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.*	

razvrstitev izdelka *Product class*	Razred IIa *Class IIa*
Osnovni UDI-DI *Basic UDI-DI*	++EBGOResins-permanentFA
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*	ρητίνες μόνιμες *Resins Permanent*	
όνομα προϊόντος και REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Προβλεπόμενη χρήση *Intended purpose*	είναι φωτοπολυμεριζόμενο, ρευστό συν θετικό υλικό με βάση εστέρες του μεθακρυλικού οξέος για την κατασκευή οριστικών μεμονωμένων στεφανών, σφραγισμάτων, επένθετων και επικα λύψεων. *A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.*	

ταξινόμηση προϊόντος *Product class*	Κατηγορία IIa *Class IIa*
βασικό UDI-DI *Basic UDI-DI*	++EBGOResins-permanentFA
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: 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 *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*	смоли постоянни *Resins Permanent*	
наименование на продукта и REF *Name of products and REF*	VarseoSmile Crown plus	41107, 41108, 41109, 41110, 41111, 41112, 41113, 41114, 41117, 41118, 41119, 41120, 41121, 41122, 41123, 41124
	Permanent Crown	FLPCC201, FLPCB101, FLPCA301, FLPCA201
	SprintRay Crown	SRE0205040, SRE0205041, SRE0205042, SRE0205043, SRE0205044, SRE0205045, SRE0205046, SRE0205054
Предназначение *Intended purpose*	е фотополимеризираща, течлива пластмаса на базата на естери на метакриловата киселина за изработване на постоянни единични корони, инлеи, онлеи и винири.	

	A light-curing, free-flowing plastic based on methacrylic acid esters for the production of permanent single crowns, inlays, onlays and veneers.
класификация на продукта *Product class*	Клас IIa *Class IIa*
Базовият UDI-DI *Basic UDI-DI*	++EBGOResins-permanentFA
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