EG-Zertifikat

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Vollständiges Qualitätssicherungssystem
Medizinprodukte

Registrier-Nr.: HD 60142369 0001

Berichts-Nr.: 21248670 019

Hersteller:

BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Deutschland

Produkte:

Legierungen, SLM Pulver, Fräsblanks, Lote, Drähte und Harze für den Dentalbereich

(siehe Anlage für einbezogene Produkte)

Ersetzt Zertifikat, Registrier-Nr.: HD 60141590 0001

Gültig bis: 2024-05-26

Hiermit erklärt die Benannte Stelle, dass die Anforderungen nach der Richtlinie 93/42/EWG Anhang II ohne Abschnitt 4 für die aufgeführten Produkte erfüllt sind. Der oben genannte Hersteller hat ein Qualitätssicherungssystem eingeführt und wendet es an. Dieses Qualitätssicherungssystem ist Gegenstand einer regelmäßigen Überwachung nach Anhang II Abschnitt 5 der oben genannten Richtlinie. Um Medizinprodukte der Klasse III, die Gegenstand dieses Zertifikates sind, auf den Markt zu bringen, ist eine EG-Auslegungsprüfbescheinigung nach Anhang II Abschnitt 4 erforderlich.

Gültig ab: 2019-08-28

Datum: 2019-08-28

Benannte Stelle

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH ist eine Benannte Stelle nach Richtlinie 93/42/EWG über Medizinprodukte mit der Kennnummer 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Anlage zum Zertifikat
Registrier-Nr.: HD 60142369 0001
Berichts-Nr.: 21248670 019

Hersteller:
BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Deutschland

Einbezogene Produkte:

- Edelmetallhaltige Laserschweißzusatzstoffe
- Edelmetall-Lote
- Edelmetall-Legierungen
- Edelmetallfreie Laserschweißzusatzstoffe
- Edelmetallfreie Lote
- Edelmetallfreie Legierungen
- Harze
- SLM Pulver
- Fräsblanks

Benannte Stelle

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Datum: 2019-08-28

Dipl.-Ing. (FH) D. Wiedemuth

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EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60142369 0001

Report No.: 21248670 019

Manufacturer:

BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Deutschland

Products:

Alloys, SLM Powders, Milling Blanks, Solders, Wires and Resins for the Dental Field

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60141590 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-08-28

Date: 2019-08-28

Notified Body

TÜV Rheinland LGA Products GmbH

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60142369 0001
Report No.: 21248670 019

Manufacturer:
BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Deutschland

Products included:

- additives for laser welding, precious metals
- solders, precious metal
- alloys, precious metal
- additives for laser welding, non-precious metals
- solders, non-precious metal
- alloys, non-precious metal
- resins
- SLM Powder
- Milling Blanks

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-08-28

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth

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Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 28, 2024

Notified Body Confirmation Letter
Reference: BEGOG_PLA0_HZ_2024-05-23, order #1160256

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen
Germany
SRN Number (if available): DE-MF-000005414

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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Germany

Headquarter

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Board of Management

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Thomas Weigand, Spokesman

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digital unterschrieben von Karsten Kluge
Datum: 2024.05.28 12:32:11 +02'00'

i.V. Dr. Karsten Kluge
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
++EBGOCasting-alloysEY	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOCobalt-alloysPR	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOCobalt-laserSR	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOCo-based-millingUM	IIb implantable (WET)	N/A	HD 60142369 0001 NB 0197
++EBGOMetal-braz-matUU	IIa	N/A	HD 60142369 0001 NB 0197
++EBGONickel-alloysX6	IIa	N/A	HD 60142369 0001 NB 0197
++EBGONoble-alloysX4	IIa	N/A	HD 60142369 0001 NB 0197
++EBGONoble-braz-matSH	IIa	N/A	HD 60142369 0001 NB 0197
++EBGONoble-laserCM	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOPD-with-nitro9Z	IIa	N/A	HD 60142369 0001 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
++EBGOPD-without-nitroZS	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOResins-permanentFA	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOResins-tempXN	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOSLM-Powder-AbutAD	IIb implantable (WET)	N/A	HD 60142369 0001 NB 0197
++EBGOSLM-Powder-C+B4B	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOSLMPowderPDPV	IIa	N/A	HD 60142369 0001 NB 0197
++EBGOTi-based-millingG3	IIb implantable (WET)	N/A	HD 60142369 0001 NB 0197
++EBGOTitanium-laserGK	IIa	N/A	HD 60142369 0001 NB 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/28	BEGOG_CL607_2024-05-28	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list