Certificate
of biocompatibility

Mediloy S-Co

Mediloy S-Co is a cobalt-based dental alloy for SLM process. It is suitable for the fabrication of dental restorations (e. g. crowns, bridges, metal-ceramic crowns and bridges, partial dentures). Furthermore, it is suitable for implant prosthetics (e. g. abutments, bars, secondary bar structures, screw-retained bridges) as well as orthodontic appliances (e. g. orthodontic bands, retainers, space maintainers).

Composition in % by mass:

Co	Cr	W	Mo	Si
63,9	24,7	5,4	5,0	1,0

The alloy corresponds to ISO 22674 and ISO 9693-1.
Mediloy S-Co is free of nickel, beryllium, cadmium and lead in accordance with ISO 22674.

Manufacturer:

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

Production:

Mediloy S-Co is produced in accordance with ISO 9001 and ISO 13485 and is approved as a class IIb medical device in the EU as well as having been certified by TÜV Rheinland (CE 0197).

Mechanical properties:

The mechanical requirements in accordance with ISO 22674 have been satisfied.

Tests and results:

Corrosion
A corrosion resistance test in accordance with the ISO 22674 “Metallic materials for fixed and removable restorations and appliances” standard has been performed. The value recorded was considerably lower than the threshold value for the ion release (corrosion) of 200 µg/cm² in 7 days defined by the standard. The corrosion resistance and intra-oral biocompatibility are thus confirmed.

Cytotoxicity
A test for potential cytotoxicity in accordance with the internationally applicable ISO 10993-5 standard has been performed. No cytotoxic potential was determined.

Final evaluation:

It is hereby confirmed that the material has been evaluated in accordance with the internationally applicable EN ISO 10993-1: “Biological evaluation of medical devices” standard. The evaluation includes, amongst other things, possible risks such as cytotoxity, sensitisation, irritation and genotoxicity.

The tests conducted were performed in independent testing facilities in accordance with the specifications of the OECD guidelines and in compliance with the GLP (Good Laboratory Practice) requirements.

The evaluation confirms the biological compatibility of Mediloy S-Co when used in accordance with the intended purpose.

Date of issue:

June 15th, 2017

Volker Voigt
Technical Director

BEGO Bremer Goldschlägerei
Wilhelm Herbst GmbH & Co. KG

Dr. Roland Strietzel
Medical Devices Safety Officer

BEGO Bremer Goldschlägerei
Wilhelm Herbst GmbH & Co. KG

F-50/021

DECLARATION OF CONFORMITY

according to annex II without 4, 93/42/EEC

- Manufacturer:

BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1
28359 Bremen, Germany
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We herewith declare under sole responsibility that the product

- Name of product family: **SLM Powders**
- Name of products: **Mediloy S-Co**
- REF number: **50551**
- Product class: **Class IIb**

meets the relevant requirements of the EC Directive **93/42/EEC** concerning medical devices

and is in conformity with the list of applied standards in the technical documentation.

This declaration of conformity is valid until expiration of the EC-Certificate 93/42/EEC (Number HD 60142369 0001) on 26 May 2024 and only together with the related batch release document.

- Notified body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

Notified body: CE 0197

Bremen, 28.05.2021

Place, Date

Signature
Chief Developer and Innovation Officer

Signature
Director of Quality Management and Regulatory Affairs

Signature
CEO