

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Bisico Bielefelder Dentsilsilicone GmbH & Co. KG
Johanneswerkstr. 3
33611 Bielefeld
Germany

With its facility as per attachment 2

has introduced, applies and maintains a Quality Assurance System
for the products / product categories:

Dental materials as per attachment 1

The compliance of the Quality Assurance System with the below mentioned
requirements of the **Council Directive 93/42/EEC** was verified by an audit:

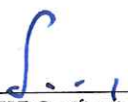
Annex V

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 23 February 2024

Report No.: 1962FS20F
Process No.: QS – 1962
Certificate No.: 1962GB414190412

Hamburg, 12 April 2019



MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-237.10.15

Attachment 1
EC-Certificate of Conformity
QS - 1962

This attachment is valid only in connection with certificate No: 1962GB414190412

Bisico Bielefelder Dentsilsilicone GmbH & Co. KG
Johanneswerkstr. 20
33611 Bielefeld
Germany

Hamburg, 12 April 2019



MEDCERT Certification Body
(Dr. Andreas Schich)



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-237.10.15

Attachment 2

EC-Certificate of Conformity

QS - 1962

This attachment is valid only in connection with certificate No: 1962GB414190412

- **Materials for temporary crowns and bridges**
- **Dental cements**
- **Primer and bonding systems**
- **Filling materials**
- **Core build-up materials**
- **Etching materials**
- **Relining material for dentures**
- **Varnishes**

Hamburg, 12 April 2019



MEDCERT Certification Body
(Dr. Andreas Schich)



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-237.10.15