

EC-CERTIFICATE

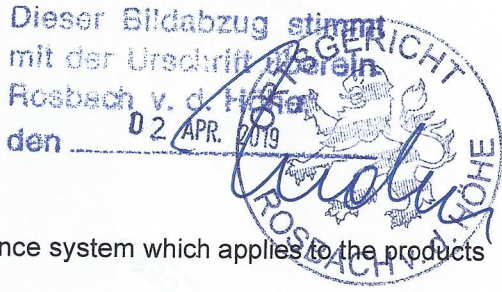
(Full quality assurance system)



This is to certify that the company

Schütz Dental GmbH

Dieselstr. 5-6
61191 Rosbach
Germany



has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Dental devices according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	230467 MR2
Certificate unique ID	170703797
Effective date	2018-10-12
Expiry date	2023-10-11
Frankfurt am Main	2018-10-12

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland
Diese öffentliche Urkunde
2. ist unterschrieben von Reinhard Zeidler
3. in seiner Eigenschaft als Ortsgerichtsvorsteher
4. sie ist versehen mit dem Siegel/Stempel des(der)
Ortsgerichts Rosbach v. d. Höhe

Bestätigt

5. in Gießen
6. am 7. Oktober 2019
7. durch die Frau Präsidentin des Landgerichts
8. unter Nr. 910 E 2- 1133/2019
9. Siegel/Stempel
10. Unterschrift

Schmidt-Nentwig
Schmidt-Nentwig

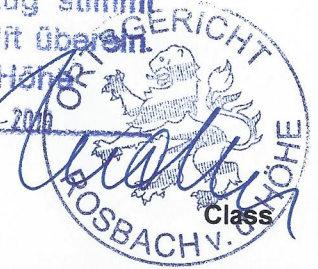


Annex to certificate
Certificate registration No.: 230467 MR2
Certificate unique ID: 170703797
Effective date: 2018-10-12

Schütz Dental GmbH

Dieselstr. 5-6
 61191 Rosbach
 Germany

Dieser Bildabzug stimmt
 mit der Urschrift überein.
 Rosbach v. d. Höhe
 den 02 APR 2018



Device family	Device	Class
Dental device	Attachment glue	Ila
	Dental alloys and metals	Ila
	Dental solder and welding wire	Ila
	Fixing composite / root pin cement	Ila
	Dental connectors (attachments for dental fixed restorations)	Ila
	Galvano gold liquid	Ila
	Light curing denture lacquer	Ila
	Resin based dental colors	Ila
	Denture base materials	Ila
	Resin facing material	Ila
	Dental ceramic material	Ila
	Rotating instruments, abutment accessories for The IMPLA implant system	Ila
	Dental filling material on composite basis	Ila
	Temporary crown and bridge material	Ila
	Dental bleaching gel	Ila
	Dentin bonding	Ila
	Dental etching gel	Ila
	Ceramic repair material	Ila
	Millable preshaped parts for all-ceramic dental restorations	Ila
	IMPLA implant system	Ilb
	Dental colors for individualization	Ila
	Millable preshaped plastic parts for dental restorations	Ila
	Framework covering material	Ila
	Bonding agent	Ila
	Millable CAD/ CAM materials	Ila



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