



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Schilli
Implantology
Circle



SIC invent AG

Birmannsgasse 3
4055 Basel
Switzerland

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 Implants, Abuments, Accessories as listed in the 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.	293238 MR2
Certificate unique ID	170660686
Effective date	2017-01-01
Expiry date	2021-12-31
Frankfurt am Main	2016-12-09

DQS Medizinprodukte GmbH

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



Annex to certificate
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Device family	Device	Class
Dental Implants, Abutments and Accessories	Cylindrical and conical Screw Implants	IIb
	Fixation Screws, Cover Screws	IIb
	Fixation Screws for Cover Screws	IIb
	Bone Drills, Crestal Drills and Bone Taps	IIa
	Gingiva Shapers	IIb
	Prosthetic Abutments	IIb
	Bioresorbable bone filling material SIC Nature Graft	III