QS
QUALITY SERVICE

EC-CERTIFICATE

Full Quality Assurance System
(Annex II with the exemption of section 4 of the Directive 93/42/EEC on Medical Devices)
Registration No. 13225

Dr. Ihde Dental AG
CH-8737 Gommiswald

The Notified Body of QS Zürich AG hereby declares that the aforementioned manufacturer has established a quality assurance system according to annex II (with the exemption of section 4) of the Directive 93/42/EEC for medical devices and the corresponding national legislation for medical devices.
We confirm, verified by means of an audit, that the quality system conforms to the relevant provisions of the aforementioned directive.

This EC-Certificate is only valid for the following product lines:
(The products are specified in annex „Product range".
This Certificate is only valid together with this annex)

Two-part Implant systems
Single-piece Implant systems

During the validity of this Certificate, the requirements of the above mentioned regulations must be fulfilled permanently. This is supervised by QS ZÜRICH AG

For precise and updated information concerning possible changes occurred in the certification object of the present certificate, please contact info@quality-service.ch

CE 1254

Valid from: 22.03.2017

Issue date: 22.03.2017

Valid until: 21.03.2020

QS Zürich AG
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Management

QS ZÜRICH AG
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Product Range and Area of Application of the Certificate of Conformity for Medical Devices

Company (Name / street / postal code / locality / country):		Dr. Ihde Dental AG, Dorfplatz 11, CH-8737 Gommiswald					
Reference Number Conformity Assessment Procedure:		V-15.1762C				Registration Number Conformity Attest / Certificate:	13225
Identification Product Group / Product:		Two-part Implant systems Single-piece Implants systems					
Class according to directive 93/42/EEC:		IIb/ IIa				Assessment according to Annex of the directive 93/42/EEC:	Annex II with the exemption of section 4
No.	Product Identification (Trade name, type, batch-, part-, order number, design)	Sterile	Measuring function	Active	Class	Manufacturing process with special requirements (sterilization, packing, testing ...)	Referenced standards
1	Two-part Implant systems (SSO, STW, STO, BLP, XIGN, HEXACONE)	Yes	No	No	IIb	Devices are packed and gamma sterilized.	DIN EN ISO 13485 ISO 15223-1 DIN EN 1041 DIN EN ISO 14971 DIN EN 62366 DIN EN ISO 10993-1 DIN EN ISO 10993-5 DIN EN ISO 10993-10 DIN EN ISO 11137-1 DIN EN ISO 11137-2 DIN EN ISO 11737-1 DIN EN ISO 11607-1 DIN EN ISO 11607-2 DIN EN ISO 14644-1 DIN EN ISO 17664 ISO 1641 DIN ISO 5832-1 DIN EN ISO 5832-2 DIN EN ISO 5832-3 ASTM F67-13 ASTM F1044-05 ASTM E468-11 ASTM E466-15
2	Single-piece Implant systems (KOS, BCS, ZSI)	Yes	No	No	IIb	Devices are packed and gamma sterilized.	
3	Abutments and adapters	No	No	No	IIa	Devices are packed	
4	Surgical drills	No	No	No	IIa	Devices are packed	

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							ASTM F67-13 ASTM F136-13 ASTM B348-13 ASTM B229-12 ASTM F1537-11 ASTM F1185-03 ASTM F1980 DIN EN 1639 DIN EN 1642 DIN EN ISO 2157 DIN EN ISO 3823-1 DIN EN ISO 7405 DIN EN ISO 6360-3 DIN EN ISO 10451 EN ISO 14801 ISO 5835 DIN EN ISO 14630 DIN EN ISO 16061

The completeness and correctness of this table is confirmed
(Stamp of the Inspection Body / Date / Signature):

NOTIFIED BODY
QS
QUALITY SERVICE
CE 1254
QUALITY SERVICE SWITZERLAND

22 May 2017