



Certificate

No. Q5 082649 0001 Rev. 02

Holder of Certificate:



DENTSPLY Implants Manufacturing GmbH

Rodenbacher Chaussee 4
63457 Hanau
GERMANY

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of products for dental implantology

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 082649 0001 Rev. 02

Report No.: 713189248

Valid from: 2021-02-16

Valid until: 2024-01-31

Date, 2021-02-16

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 082649 0001 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

DENTSPLY Implants Manufacturing GmbH
Rodenbacher Chaussee 4, 63457 Hanau, GERMANY

Production of products for dental implantology

DENTSPLY IH AB
Aminogatan 1, 43121 Mölndal, SWEDEN

Design and development, production and distribution of products
for dental implantology

DENTSPLY IH Inc.
590 Lincoln Street, Waltham MA 02451, USA

Design and development, production and distribution of products
for dental implantology

Sirona Dental Systems GmbH
Fabrikstr. 31, 64625 Bensheim, GERMANY

Design and development of products for dental implantology

Dentsply Sirona KK
1-5-21 Katsushima, Shinagawa-ku, Tokyo, 140-0012 JAPAN

Production and distribution of products for dental implantology

./.