ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 031247 0089 Rev. 01

Manufacturer: **Sirona Dental Systems GmbH**
Fabrikstr. 31
64625 Bensheim
GERMANY

SRN Manufacturer: DE-MF-000000029

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 031247 0089 Rev. 01

Report No.: 713216744

Preceding Certificate No.: G10 031247 0089 Rev. 00

Valid from: 2021-11-12
Valid until: 2025-07-13

Date of Initial Issuance: 2020-07-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-11-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	IIa
Device Group:	Z12110180 - INSTRUMENTS FOR DENTAL TREATMENT UNITS - HARDWARE
Intended Purpose:	-
Classification:	IIb
Device Group:	Z12011016 - DIODE LASERS
Intended Purpose:	Diode Laser for dental applications
Classification:	IIa
Device Group:	Z11069082 - VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - SOFTWARE
Intended Purpose:	-
Classification:	IIa
Device Group:	P01020180 - DENTAL IMPLANTS - ACCESSORIES
Intended Purpose:	-
Classification:	IIb
Device Group:	Z110311 - DIRECT DIGITAL X-RAY SYSTEMS
Intended Purpose:	Dental imaging device
Classification:	IIa
Device Group:	Z12110101 - DENTAL TREATMENT UNITS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report
00	2020-07-14	713171243

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