



Document Detail

Type: 2000-ISO
Document No.: 2000-ISO-0066[01]
Title: Dentsply Sirona Orthodontics Inc. (Sarasota, Florida) EC MDD Certificate
Comment: Refer to scope reduction notification and redline of certificate for changes made from the version 0280-SUP
Status: CURRENT
Effective Date: 21-Apr-2021

Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
2000-Document Control Orthodontic SBU Document Control	Tessa Lee	20-Apr-2021 8:58 pm	GMT
2000-Regulatory Compliance Appvr Orthodontics Regulatory Compliance Approver	Laura Sobrin	20-Apr-2021 10:02 pm	GMT
2000-Document Control Orthodontic SBU Document Control	Tessa Lee	21-Apr-2021 12:59 pm	GMT

Reference

<u>Document No.</u>	<u>Title</u>	<u>Relation</u>
0280-OF-NOTF-0065 [4]	Change Notification to TUV Sud of Scope Reduction of DSO pr	Related



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 103315 0010 Rev. 00

Manufacturer: **Dentsply Sirona Orthodontics Inc.**
7290 26th Court East
Sarasota FL 34243
USA

Product Category(ies): **Thermoforming Plastic Sheets,
Interproximal Reduction System, including
Dental Burs, Dental Appliance
Cleaner/Disinfectant (Tablets).**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G11033150010Rev.00

Report No.: 72163620

Valid from: 2021-04-20

Valid until: 2024-05-26

Date, 2021-04-20

Christoph Dicks
Head of Certification/Notified Body