

Declaration of conformity

C € 0123

Manufacturer

Address

Ivoclar Vivadent AG

Bendererstrasse 2 9494 Schaan Liechtenstein

Product

SR Phonares® II

Type of material

Resin Teeth

Product category

Resin Teeth

Classification

Medical Device Class IIa

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directives

Medical Device Directive 93/42/EEC, Annex II. 3

Notified Body

Address

TÜV SÜD Product Service GmbH

Ridlerstrasse 65 80339 München

Deutschland

Place, Valid from

Schaan, 2016-09-16

Replaces version of: 2015-01-16

Valid until

2021-08-07

Signature

Name

Position

Dr. Thomas Hirt

CTO

Dipl. Ing. Patrik Oehri Director CQM and Regulatory Sicherheitsbeauftragter

(Product Safety Officer)

Date

2016-09-16

2016-09-16



Attachment to Declaration of conformity

Product	SR Phonares [®] II
Dated	2016-09-16
639350 639351 639352	SR Phonares II Ant. set of 6 SR Phonares II Lingual set of 8 SR Phonares II Typ set of 8

Place, Valid from

Schaan, 2016-09-16

Replaces version of: 2015-01-16

Signature

Name Position Dr. Kathrin Fischer Scientific Service, R&D

Date

2016-09-16

Sandra Cakebread Regulatory Affairs, R&D

2016-09-16