

Declaration of Conformity

CE 0123

Manufacturer Address	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan Liechtenstein
Product	SR Ivocap Clear SR Ivocap High Impact
Type of material	Denture base material
Product category	Denture base materials
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.

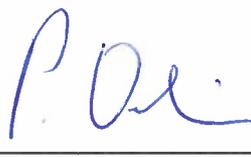
Directives	Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
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Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
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Place, Valid from	Schaan, 2021-05-25 Replaces version of: 2016-09-22
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Valid until	2024-05-26
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Signature

Name
Position

Dr. Thomas Hirt
CTO

Dipl. Ing. Patrik Oehri
Director CQM and Regulatory
Sicherheitsbeauftragter
(Product Safety Officer)

Date

2021-05-25

2021-05-25

Attachment to Declaration of Conformity of
SR Ivocap Clear

Article No.	Description	MD Classification (EU)	Rule (EU)
530205XN	SR Ivocap Standard Kit clear	Class II a	5

Schaan, 13.02.2024

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Attachment to Declaration of Conformity of
SR Ivocap High Impact

Article No.	Description	MD Classification (EU)	Rule (EU)
531396AN	SR Ivocap High Impact Standard Kit Pink	Class II a	5
531402AN	SR Ivocap High Impact Standard Kit US-L	Class II a	5
531403AN	SR Ivocap High Impact Standard Kit US-P	Class II a	5
531404AN	SR Ivocap High Impact Standard Kit S	Class II a	5
531451AN	SR Ivocap High Impact Stand. Kit Pink-V	Class II a	5
559615AN	SR Ivocap High Impact Standard Kit Pref.	Class II a	5
578936AN	SR Ivocap High Impact Standard Kit US-D	Class II a	5
629097AN	SR Ivocap HI Standard Kit Pink-V Implant	Class II a	5
629288AN	SR Ivocap HI Standard Kit Pref. Implant	Class II a	5

Schaan, 13.02.2024

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