ivoclar vivadent®
passion vision innovation

CE 0123

Declaration of Conformity

Manufacturer Address	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan Liechtenstein
Product	**IvoBase High Impact** **IvoBase Hybrid**
Type of material	Denture base material
Product category	Denture base material
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)
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
Place, Valid from	Schaan, 2021-05-25 Replaces version of: 2017-03-27
Valid until	2024-05-26

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

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Attachment to Declaration of Conformity of

IvoBase HI / IvoBase Hybrid

Article No.	Description	MD Classification (EU)	Rule (EU)
628883AN	IvoBase Hybrid Kit 20 Pink	Class II a	5
628884AN	IvoBase Hybrid Kit 20 Pink-V	Class II a	5
628885AN	IvoBase Hybrid Kit 20 Preference	Class II a	5
628886AN	IvoBase Hybrid Kit 20 Pink-V Implant	Class II a	5
628887AN	IvoBase Hybrid Kit 20 Preference Implant	Class II a	5
628888AN	IvoBase Hybrid Kit 20 Clear	Class II a	5
628889AN	IvoBase HI Kit 20 Pink	Class II a	5
628890AN	IvoBase HI Kit 20 Pink-V	Class II a	5
628891AN	IvoBase HI Kit 20 Preference	Class II a	5
628892AN	IvoBase HI Kit 20 Pink-V Implant	Class II a	5
628893AN	IvoBase HI Kit 20 Preference Implant	Class II a	5
640933AN	IvoBase HI Kit 20 34-V	Class II a	5

Schaan, 13.02.2024

(this document is valid without signature)

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.