

Declaration of Conformity


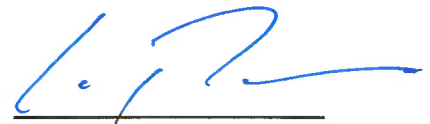
Manufacturer Ivoclar Vivadent AG
Address Bendererstrasse 2
9494 Schaan
Liechtenstein

Product **Bluephase PowerCure**

Type of material Dental curing light

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	93/42/EEC	Medical Devices Directive, Annex II excluding (4)
	2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
Standards	IEC 60601-1:2012	Medical electrical equipment Part 1 General requirements
	IEC 60601-1-2:2007	Medical electrical equipment Part 1-2 Electromagnetic compatibility
	ISO 10650:2015	Dentistry - Powered polymerization activators
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland	
Place, Valid from	Schaan, 2021-05-25 Replaces version of: 2018-12-11	
Valid until	2024-05-26	
Signature		
Name Position	Dipl. Ing. Patrik Oehri Director R&D Services	Dipl. Ing. Gottfried Rohner Director Equipment Development
Date	2021-05-25	2021-05-25