

EU-Konformitätserklärung

EU Declaration of Conformity



Document No.: GC 124 / 05

Manufacturer:	Sirona Dental Systems GmbH
Address:	Fabrikstraße 31 64625 Bensheim
device:	CEREC Primemill
Product identification (e.g. Part number / Diagram-No.):	Model-No.: D3692 Ref.-No.: See page 2 of this DoC Serial-No.: > 601000

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Radio Equipment Directive (RED) 2014/53/EU. (OJEU L 153/62, 22.05.2014)

We declare the compliance of the device concerned with the requirements of the Council Directive 2006/42/EC Machinery Directive, 2014/30/EC EMC Directive and 2011/65/EU RoHS Directive including 2015/863/EC as annex II.



Any modification to the product, not authorized by us, will invalidate this declaration.

The following (parts/clauses of) standards have been applied:

ETSI EN 301 489-3 V2.1.1 (2017-03)
DIN EN 61010-1:2011-07
DIN EN ISO 14971:2013-04
DIN EN 61326-1:2013-07

The VDE Testing and Certification Institute NB-RED (notified body with code 0366) performed an EU-type examination and issued the EU-type examination certificate: 40050675

Valid from manufacturing date: 2021-10-01

Bensheim, 28.09.2021	
Place and date	
	
[Signature]	[Signature]
[Printed Name] Mr. Niels Plate	[Printed Name] Mr. Wolfgang Eiff
Group Vice President	Regulatory Compliance Manager

The declaration certifies the compliance with the Directive. Conditions of guarantee and liability are dealt within our General Conditions of Sale.

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Product Models	Product Name / Product Variants	
6617570	CEREC Primemill consisting of one of the following product variants	
	6617620	CEREC Primemill
6748169	CEREC Primemill, B-Ware consisting of one of the following product variants	
	6748151	CEREC Primemill B-Ware Base Unit
6726561	CEREC Primemill US	