## 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

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 EUtype examination and issued the EU-type examination certificate: 40050675

Valid from manufacturing date: 2021-10-01

Bensheim, 28.09.2021

Place and date

[Printed Name] Mr. Niels Plate

Group Vice President

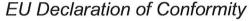
[Signature]

[Printed Name] Mr. Wolfga

Regulatory Compliance Manager

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

## **EU-Konformitätserklärung** *EU Declaration of Conformity*





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	