

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 738262 R000

Manufacturer: exocad GmbH

Address:

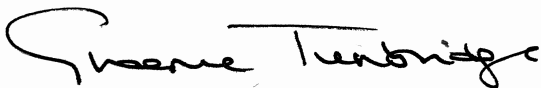
Landwehrstraße 54
Darmstadt
64293
Germany

Single Registration Number: Not Available

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-04-08**

Date: **2022-04-08**

Expiry Date: **2027-04-07**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Dental Restoration Devices - ChairsideCAD (incl. AbutmentCAD module) / Ceramill Mind DRS (incl. Ceramill M-Plant module)	Class IIa



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3313725	Issued



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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 738262 R000

Date: 2022-04-08

Critical Subcontractor/Crucial Supplier	Service(s) supplied
exocad GmbH Julius-Reiber-Str. 15 Darmstadt 64293 Germany	Design Development
exocad GmbH Dolivostraße 17 Darmstadt 64293 Germany	Design Development

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