

# EU Quality Management System Certificate

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

## MDR 759293 R000

**Manufacturer:** Dentscare Ltda

**Address:**

Av. Edgar Nelson Meister, 474  
Distrito Industrial  
Joinville  
Santa Catarina  
89219-501  
Brasil

**Single Registration Number:** BR-MF-000004013

**EU Authorised Representative:** Nuno Flores

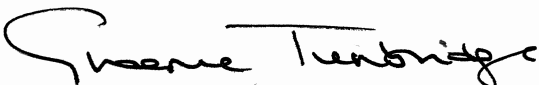
**Address:**

Alameda Bonifacio Lazaro Lozano, 3 Piso 0 C  
Oeiras  
2780-125  
Portugal

**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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2025-03-31**

Current Issue Date: **2025-03-31**

Starting Validity Date: **2025-03-31**

Expiry Date: **2030-03-30**

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### Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental Implants	Intended to be fixed exclusively in dental bone tissue (mandible or maxilla), and to serve as support and stability for fixed and/or movable prosthetic restorations (single, multiple or hybrid).
Dental Abutments and Accessories	Intended to be used as intermediaries between the dental implant and prosthesis, designed specifically for each case to respect prosthetic interfaces and ensure optimal aesthetics and function.

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

Device(s)	Risk Classification
Implantable dental restoration devices	Class IIa, implantable
Non-implantable dental cements	Class IIa
Reusable dental instruments, non-sterile, connected to an active device	Class IIa

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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	3555385	Issued



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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.