

# EU Quality Management System Certificate

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

## MDR 747250 R000

**Manufacturer:** LOGON OMF Bioactive Systems GmbH

**Address:**

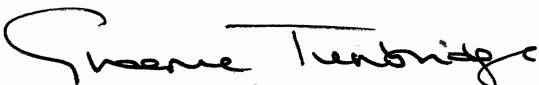
Esslinger Straße 6  
Pforzheim  
75179  
Germany

**Single Registration Number:** DE-MF-000006289

**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 Medical Devices

First Issue Date: **2023-04-17**

Current Issue Date: **2023-04-17**

Starting Validity Date: **2023-04-17**

Expiry Date: **2028-04-16**

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

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental implants	Intended for use in the upper and lower jawbone and are used to anchor or fasten dentures to restore the chewing function
Abutments and prosthetic accessories	The straight and angled abutment is used for conventional crown and bridge technology. The straight and angled hybrid prosthetic abutment is used for conventional bar technology.
Healing abutments	Used for soft tissue reconstruction during implant healing. They are screwed directly into the implant.

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

Device(s)	Risk Classification
Odontostomatology cutting instruments	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	3411786	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.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
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