EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Certificate no. 085/MDR

On the basis of the assessment carried out according to Annex IX, chapter II, of the Regulation (EU) 2017/745, we hereby certify that the technical documentation:

of the Manufacturer: **NUEVA GALIMPLANT, SLU**

27600 SARRIA – LUGO - C/ BENIGNO QUIROGA,90 (ESP) - Spain

SRN: ES-MF-000000406

for the following devices:

Dental implants

complies with the applicable requirements of the aforementioned EU Regulation.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date:	2023-02-08
Previous issue date:	2023-02-08
Current issue date:	2023-07-21
Expiry Date:	2028-02-07

IMQ

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Certificate no. 086/MDR

On the basis of the assessment carried out according to Annex IX, chapter II, of the Regulation (EU) 2017/745, we hereby certify that the technical documentation:

of the Manufacturer: **NUEVA GALIMPLANT, SLU**

27600 SARRIA – LUGO - C/ BENIGNO QUIROGA,90 (ESP) - Spain

SRN: ES-MF-000000406

for the following devices:

Abutment

complies with the applicable requirements of the aforementioned EU Regulation.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

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EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 087/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: **NUEVA GALIMPLANT, SLU**

27600 SARRIA – LUGO - C/ BENIGNO QUIROGA,90 (ESP) - Spain

SRN: ES-MF-000000406

for the following devices:

Dental implants

Abutment

Prosthetic dentistry accessories

Surgical instruments for dental implantology

Reusable surgical instruments for dental use

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date:	2023-02-08
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IMQ