



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: 2023-07-21
 Current issue date: 2025-12-19
 Expiry Date: 2028-02-07



IMQ

Pag. 2 di/4