



EC CERTIFICATE

Certificate No 2025/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

BIOSTAR LABORATORIOS, S.L.U.

28021 MADRID - C/ LAGUNA DEL MARQUESADO 19, Planta 2 (ESP) - Spain

manages in the factory of:

28320 PINTO (MADRID) - CALLE GARZAS 18 (ESP) - Spain

a quality assurance system ensuring the conformity of the following products:

Dental implants

Prosthesis for dental implants

Tools for dental bone surgery

Type ref. as to document 'Annex of EC Certificate no. 2025/MDD - Device List' rev. 0 dated 2021/03/04; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM18-0024320-01; DM20-0048289-01; DM20-0049036-01; DM20-0052860-01; DM21-0061386-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2019-03-12
 Updated: 2021-03-04
 Substitution Date: 2020-06-17
 Expiry Date: 2024-03-11



IMQ DocuSign