



EC CERTIFICATE

Certificate No 1334/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:

TERRATS MEDICAL, S.L.

08210 BARBERÁ DEL VALLÉS (BARCELONA) - C/MOGODA 75-99 POL. IND. CAN SALVATELLA (ESP) - Spain

manages in the factory of:

08210 BARBERÁ DEL VALLÉS (BARCELONA) - C/MOGODA 75-99 POL. IND. CAN SALVATELLA (ESP) - Spain

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

Clinical screws

Interfaces and abutments

Dental implants

Dental surgical drills

Dental rotary instruments

Type ref. as to document 'Annex of EC Certificate no. 1334/MDD - Device List' rev. 1 dated 2021/05/17; 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:

10AK00056; 10AK00176; 10AL00121; 10AM00019; 10EM00065, 10AN00052; DM15E0390698-01; DM16A0619189-01; DM17-0013766-01; DM18-0023270-01; DM18-0030772-01; DM19-0034781-01; DM19-0038065-01; DM20-0049585-01; DM20-0049321-01; DM21-0061235-01; DM21-0064939-01.

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: 2010-05-25
 Updated: 2021-05-17
 Substitution Date: 2021-03-10
 Expiry Date: 2024-05-26

IMQ