



EC CERTIFICATE

Certificate No 1153/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:

BIONER, S.A.

28003 MADRID - C/ GALILEO 91 4 PLANTA DESPACHO 5 (ESP) - Spain

manages in the factory of:

08960 SANT JUST DES VERN (BARCELONA) - C/ L'ESPIGOLERA 9 (ESP) - Spain

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

Abutment

Dental implants

Cover screws

Clinical screws

Healing abutment

Dental drills

Transepithelial connectors

Kit for dental grafts

series and type refs in the Annex

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 IMG files Nos:

10AI00011; 10AN00083; 10AN00091; 10AO00075; DM18-0021386-01; DM18-0024324; DM17-0009874-01; DM18-0031343-01; DM19-0043046-01; DM19-0044643-01.

This Approval Certificate is issued by IMG 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:	2008-06-08
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IMG