

TECHNICAL OFFICE FOR MEDICAL DEVICES CERTIFICATION
Organization notified according to Council Directive 93/42/CEE for medical devices with
identification number 1868

CERTIFICATE

ISO 13485

No. 25 SM 1

OTDM CERTIFICATION, accredited by the National Accreditation Organization RENAR,
certifies that:

NATIONAL INSTITUTE FOR RESEARCH AND

DEVELOPMENT IN ELECTRICAL ENGINEERING

ICPE-CA

Str. Splaiul Unirii no.313, sector 3, Bucharest, Romania

has establish and maintains a Quality Management System that meets the standard SR EN ISO
13485:2004; SR EN ISO 13485:2004/AC:2010, for:

Research, design, development, fabrication of medical devices
(bone substitute)

Audit report no. 25-A2/25.11.2012

Committee Chairman to Ensuring the Impartiality
Ing Lazăr IORDACHE

Manager
Ing. Ioana Tene

20.12.2012
Date of the first edition

19.12.2015
The expiration date

The validity of this certificate is conditional upon annual surveillance
Bd. Nicolae Titulescu 58, sector 1, Bucuresti
www.otdm-certificare.ro

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EC CERTIFICATE
COMPLET SYSTEM QUALITY ASSURANCE
(Anexa II, section 3, Council Directive 93/42/CEE for medical devices, revised)

No. 25 DM 2.3

This certificate is awarded manufacturer:

NATIONAL INSTITUTE FOR RESEARCH AND
DEVELOPMENT IN ELECTRICAL ENGINEERING ICPE-
CA

Str. Splaiul Unirii no.313, sector 3, Bucharest, Romania

For the following medical devices:

Granular product beta tricalcium phosphate, PG β -TCP

-Used in oral and maxillofacial surgery to fill the bone defect and bone augmentation

OTDM CERTIFICATION declare that the examination of full quality assurance system was conducted in accordance with Annex II section 4 of Directive 93/42/EEC relating medical devices, with subsequent modifications, transposed in GD no.54/2009 on conditions for placing on the market of medical devices. We certify that the complete quality assurance system complies with the relevant provisions of the directive.

For market introduction of the products mentioned above, this certificate is valid only if accompanied by the EC certificate product review project no. 25 DM 2.4/ 20.12.2012.

Underlying documents for granting certification are:

- **Inspection report no. 25-I / 08.11.2012**
- **Audit report no. 25-A2 / 05.11.2012**
- **Minutes of the Technical Committee for Evaluation**

Committee Chairman to Ensuring the Impartiality
Ing Lazăr IORDACHE

Manager
Ing. Ioana Tene

20.12.2012
Date of the first edition

19.12.2017
Expiration date

Continued validity of the certificate shall be in accordance with Annex II, section 5, DDM 93/42/CEE and the Certification Contract no. 25 DM/ 08.11.2011; CE₁₈₆₈ marking can be applied only to medical devices specified in the certificate of conformity

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EC CERTIFICATE

PRODUCT DESIGN REVIEW

(Anexa II, section 4, Council Directive 93/42/CEE for Medical Devices, revised)

No. 25 DM 2.4

This certificate is awarded manufacturer:

NATIONAL INSTITUTE FOR RESEARCH AND DEVELOPMENT IN ELECTRICAL ENGINEERING ICPE-CA

Str. Splaiul Unirii nr.313, sector 3, Bucharest, Romania

For the following medical devices:

Granular product beta tricalcium phosphate, PG β -TCP

-Used in oral and maxillofacial surgery to fill the bone defect and bone augmentation

OTDM CERTIFICATION declares that the product design review was conducted in accordance with Annex II section 4 of Directive 93/42/EEC relating medical devices, with subsequent modifications, transposed in GD no.54/2009 on conditions for placing on the market of medical devices.

We certify that the product design complies with the relevant provisions of the directive.

Necessary data for identification of the approved design, medical devices covered by the certificate (brand and model) and examinations performed are found in the Report of examination of the design dossier no. 25-P/14.12.2012, which form part of this certificate.

Committee Chairman to Ensuring Impartiality
Ing Lazăr IORDACHE

Manager
Ing. Ioana Tene

20.12.2012
Date of the first edition

19.12.2017
Expiration date

Continued validity of the certificate shall be in accordance with Annex II, section 5, DDM 93/42/CEE and the Certification Contract no. 25 DM/ 08.11.2011