



NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlín, Czech Republic

EC CERTIFICATE

No. 06 0386 QS/NB

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the products – medical devices of Class IIb

Alumina Based Ceramic Femoral Head,
types Standard Neck 26 mm, 28 mm and 32 mm

Placed on the market by company

IFGL BioCeramics Ltd.

McLeod House 3, N.S. Road 700001 Kolkata, India

Manufactured by company

IFGL Refractories Ltd.

Unit 1, Sector A, Kalunga Industrial Estate, Sundergarh, 770031 Orissa, India

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system. The quality system has been assessed, approved and it is a subject of the continuous surveillance according to Annex II, Sections 3.3. and 5. of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600149/2006, which is an integral part of this Certificate.

This Certificate is issued under following conditions:

- 1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 30th September 2009 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. The manufacturer shall affix to each medical device of the above referenced type the conformity mark CE followed by number of Notified Body according to an example:*

CE 1023



Mr. Pavel Voj

RNDR. Radomír Čevelík

Representative of the Notified Body No. 1023

Issued in Zlín, on 1st August 2006



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Ca - Hydroxyapatite Orbital Implant,
Enucleation and Evisceration Models, diameters 12 to 20 mm
Dental Power for Bone Regeneration
Particle Size 250 – 350 μm and 350 – 500 μm

Placed on the market by company

IFGL BioCeramics Ltd.
McLeod House 3, N.S. Road 700001 Kolkata, India

Manufactured by company

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- 1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 31st July 2011 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. The manufacturer shall affix to each medical device of the above referenced type the conformity mark CE followed by number of Notified Body according to an example:*

CE 1023



Paul Voj

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

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