



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

EC Design-Examination Certificate

No. 07 0142 CN/NB

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 Coll., certifies that the product – medical device of Class III

G-BONE Synthetic Hydroxyapatite (*made from chemical only*)
(For detail specification refers Annex)

manufactured by

G . Surgiwear Limited

Rasoolpur Jahangunj, Shahjahanpur-242001, U.P., INDIA

Id. No.: 3/SC/P of 1995 and 37 of 1997

Tax registration id.: LKNG05137G

fulfils the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to Article 4, Annex II of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the ITC's Final Report No. 803600175/2007.

This Certificate is issued under following conditions:

1. *It applies only to the design of above referenced model of medical device.*
2. *It does not imply that the Notified Body has performed any surveillance or control of its manufacture.*
3. *The Certificate remains valid until the approved design is changed but until the 20th March 2012 at the latest.*
4. *Having in possession a complementary EC Certificate confirming the manufacturer's quality system approval by Notified Body No. 1023, the manufacturer shall affix to each medical device of this type the conformity CE marking followed by number of Notified Body according to an example:*

CE 1023




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

Issued in Zlín, on 21st March 2007

Annex to EC Design Examination Certificate No. 07 0142 CN/NB

issued for the company:

G. Surgiwear Limited

Rasoolpur Jahangunj, Shahjahanpur-242001, U.P., INDIA

Id. No.: 3/SC/P of 1995 and 37 of 1997


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List of Types covered by the EC certificate:

Product type:	Model:	Code No.
G-BONE Synthetic Hydroxyapatite granules Av. particle size (10 cc pack)	0.1-0.04 0.4-0.9mm 0.8-1.8 mm	SHAG1 SHAG 2 SHAG 3
Av. particle size (1 cc pack)	0.1-0.4 mm 0.4-0.9mm 0.8-1.8 mm	SHAG11 SHAG 12 SHAG 13
G-BONE Synthetic Hydroxyapatite Blocks Average Block size (in cm)	1 x 0.5 x 0.5 (20 nos.) 1 x 1 x 2 (5 nos) 1 x 1.5 x 2 (3 nos) 2 x 2.5 x 0.3 (1 nos) 2 x 2.5 x 0.5 (1 nos) Custom size	SHAB1 SHAB2 SHAB3 SHAB4 SHAB5
G-BONE Synthetic Hydroxyapatite Dowels	12 x 14 mm 14 x 16 mm 16 x 18 mm 18 x 20 mm 20 x 22 mm	SHAD1 SHAD2 SHAD3 SHAD4 SHAD5
G-Eye Synthetic Hydroxyapatite Eye Spheres	14 mm 16 mm 18 mm 20 mm Custom	SHAE14 SHAE16 SHAE18 SHAE20
G-Bone CPC	2 cc pack 5 cc pack Custom size pack	GBCPC1 GBCPC5

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