

Declaration of Conformity

For

The design and manufacture of BEGO OSS S (sterile porous bio-ceramic implants for replacement and supplementation of bone)

This is to certify that the above class III devices, sold under the brand name of BEGO OSS S as described in the Part Number Specification issue 11.0 Appendix-B of the Ceramisys Technical file for Bio-ceramic Implants, comply with the legislation of the UK transposing European Medical Devices Directive 93/42/EEC as amended 2007/47EC, using conformity route Annex II.

Compliance being demonstrated through a Quality System to BS EN ISO 13485 and the issue of an EC Certificate by BSI our appointed Notified Body.

For and on behalf of Ceramisys Ltd (The legal manufacturer)



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Wayne Austin (Director)

Dated: 12th April 2011

This is the full list of BEGO OSS S product codes extracted from Part Number specification 006 Appendix-A Issue 11.0

Description	Code
BEGO OSS S Small Granules (0.5-1.0mm)	
BEGO OSS S granules 0.5cc	57217
BEGO OSS S granules 1.0cc	57218
BEGO OSS S Large Granules (0.8-1.5mm)	
BEGO OSS S granules 2.0cc	57219