

# RTI Biologics, Inc.

11621 Research Circle, PO Box 2650, Alachua, FL, 32616-2650, United States

Device identification:

**Sterling® Cancellous Chips and Sterling® Cancellous Cubes, Sterling® Wedge, CANCELLO-PURE™ Wedge, CANCELLO-PURE™ 12 mm EVANS BONE WEDGE AND CANCELLO-PURE™ 6 mm COTTON BONE WEDGE. CopiOs™ Cancellous Chips, CopiOs™ Cancellous Cubes, CopiOs™ Wedge.**

Medical Purpose of Device:

**Non-load bearing bone void filling during orthopaedic and other surgical applications.**

has been assessed and certified as meeting the requirements of

## EC Directive 93/42/EEC

On Medical Devices Annex II Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC, and Directive 2003/32/EC on medical devices manufactured utilising tissues of animal origin.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to regular compliance visits.

This certificate is valid from 18 April 2008 until 30 May 2011

Issue 6

Certification is based on report number(s) PC DDE 212437 dated 23 May 2006.

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
25 June 2007	Add Sterling® Wedge and Cancellous-Pure™ Wedge.
28 September 2007	Add Cancellous-Pure™ 12 mm Evans Bone Wedge and Cancellous-Pure™ 6mm Cotton Bone Wedge. Clarify recommended storage temp on labelling.
26 September 2007	Change in packaging configuration.
31 March 2008	(i) Addition of CopiOs™ to range and changed (ii) Company Name to RTI Biologics, Inc.
27 February 2008	Change to storage temperature range, Addition of Warning to I.F.U., Notification of issuance of EDQM TSE Certificate of Suitability R0-CEP 2005-042-Rev 00

Notified Body Number 0120

Authorised by

SGS United Kingdom Ltd Systems & Services Certification  
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com  
SGS EC 04 1007  
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