



EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the Medical Devices Directive 93/42/EEC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the
stated products to ensure their conformity with the requirements of the Directive which apply to them.
The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER: OsteoTec Ltd
9 Silver Business Park
Airfield Way
Christchurch
Dorset BH23 3TA
United Kingdom

PRODUCT NAME: Skelifil

PRODUCT DESCRIPTION: Synthetic resorbable bone graft substitute

OTHER DETAILS: As own brand labelled

DESIGN DOSSIER REFERENCE: Renewal submission

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/0963569/00324

Original Approval: 30 September 2010

Current Certificate: 13 January 2014

Certificate Expiry: 8 October 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited