



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**OsteoTec Ltd
9 Silver Business Park, Airfield Way,
Christchurch, Dorset
United Kingdom**

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0963569/C

Original Approval: 24 October 2000

Current Certificate: 1 July 2014

Certificate Expiry: 30 June 2017

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ, United Kingdom.



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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 0963569/C SCHEDULE

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

OsteoTec Ltd
9 Silver Business Park, Airfield Way,
Christchurch, Dorset
United Kingdom

Class II Products

OsteoTec Silicone Finger Implant Sizers
OsteoTec Silicone Finger Implant
Extremity Implant Set
Osteo-X External Fixator

Class III Products

Bio-ceramic (HA/TCP) resorbable, bone
graft substitutes
Synthetic resorbable bone graft substitute

EC Design Examination Certificate

LRQ 0088/0963569/00276
LRQ 0088/0963569/00324

Schedule Issue: 01

Date of Schedule Issue: 1 July 2014

LRQA Notified Body Number 0088

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