



## 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.

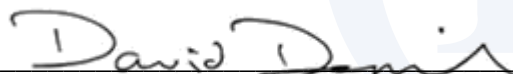
Certificate No: LRQ 0963569/C

Original Approval: 24 October 2000

Current Certificate: 1 July 2017

Certificate Expiry: 30 June 2020

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



## 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 2017  
LRQA Notified Body Number 0088



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