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, Dorest
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:	12 July 2019
Certificate Expiry:	30 September 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, Dorest
United Kingdom

Class II Products

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

Schedule Issue: 02

Date of Schedule Issue: 12 July 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited