By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 569050**

Issued To: **Musculoskeletal Transplant Foundation**
125 May Street
Edison
New Jersey
08837-9947
USA

In respect of:

The manufacture and final inspection of sterile single use kits for separation of autologous blood plasma and fibrin

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **08 March 2011** Date: **29 February 2016** Expiry Date: **07 March 2021**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 569050**
Date:	**29 February 2016**
Issued To:	**Musculoskeletal Transplant Foundation** **125 May Street** **Edison** **New Jersey** **08837-9947** **USA**

Subcontractor:	**Service(s) supplied**
DIZG Innovationspark Wuhlheide Köpenicker Straße 325, Haus 42 D-12555 Berlin Germany	**EU Representative**
Musculoskeletal Transplant Foundation 1223 Mid Valley Drive Jessup Pennsylvania 18434 USA	**Final Inspection** **Labelling**
Riverside Medical Packaging Co Ltd Newmarket Drive Derby Derbyshire DE24 8SW United Kingdom	**Assembly** **Control of Sterilization** **Packaging**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 569050**

Date: **29 February 2016**

Issued To: **Musculoskeletal Transplant Foundation**
125 May Street
Edison
New Jersey
08837-9947
USA

Date	Reference Number	Action
08 March 2011	7607491	First issue.
29 November 2012	7916505	Addition of Thorn Industries Inc as a significant subcontractor for manufacture and removal of significant subcontractor Interplex Precision Machining.
14 August 2013	7958643	Extension of scope to include autologous blood plasma and fibrin separation kits; Addition of Riverside Medical as a significant sub-contractor.
15 April 2015	8313284	Scope reduction to remove surgical instrument kit and reusable instruments for osteochondral graft transfer; Removal of the following from the list of significant sub-contractors – Thorn Industries, The Medtech Group, and Steris Isomedix.
29 February 2016	8431057	Certificate renewal.