

# 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, and sterile single use kits for processing of autologous adipose tissue.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-03-08**

Date: **2019-12-11**

Expiry Date: **2021-03-07**

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## Supplementary Information to CE 569050

Issued To:

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Number	Device name	Intended purpose per IFU
Class IIa		
SMD 0102	CASCADE Autologous Platelet Systems	n/a
SMD 0102	Lipografter system	n/a

First Issued: **2011-03-08**

Date: **2019-12-11**

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# 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:

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 Date: **2019-12-11**  
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Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	<b>EU Representative</b>
Geno Technology Inc./ G-Biosciences 9800 Page Avenue St. Louis Missouri 63132 USA	<b>Crucial Supplier</b>
Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster Austria	<b>Crucial Supplier</b>

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USA**

**Subcontractor:****Service(s) supplied**

Isomedix Operations, Inc  
3459 South Clinton Avenue  
South Plainfield  
New Jersey  
07080  
USA

**ETO Sterilization**

Isomedix Operations, Inc.  
2500 Commerce Drive  
Libertyville  
Illinois  
60048  
USA

**Gamma Sterilization**

Isomedix Operations, Inc.  
North Facility  
1880 Industrial Drive  
Libertyville  
Illinois  
60048  
USA

**Gamma Sterilization**

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Millstone Medical Outsourcing LLC 580 Commerce Drive Fall River Massachusetts 02720-4759 USA	<b>Assembly Packaging</b>
Musculoskeletal Transplant Foundation 1175 Mid Valley Drive Olyphant Pennsylvania 18447 USA	<b>Final Inspection</b>
Musculoskeletal Transplant Foundation 1232 Mid Valley Drive Jessup Pennsylvania 18434 USA	<b>Final Inspection</b>

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**Subcontractor:****Service(s) supplied**

Riverside Medical Packaging Co Ltd  
Newmarket Drive  
Derby  
Derbyshire DE24 8SW  
United Kingdom

**Assembly  
Control of Sterilization  
Packaging**

Sequel Special Products  
1 Hillside Drive  
Wolcott  
Connecticut  
06716  
USA

**Manufacture**

Sterigenics US, LLC  
84 Park Road  
Queensbury  
New York  
12804  
USA

**ETO Sterilization**

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## Certificate History

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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 subcontractor.
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.
02 August 2017	8763501	Removal of 'Labelling' as service supplied and correction of address for Musculoskeletal Transplant Foundation, 18434 Jessup. Addition of Musculoskeletal Transplant Foundation, 18447 Olyphant; Millstone Medical Outsourcing, LLC, 02720 Fall River; Steris Isomedix Services, 1880 Industrial Drive and 2500 Commerce Drive, Illinois Steris Isomedix Services, 60048 Libertyville; Steris Isomedix Services, 07080 South Plainfield; Greiner Bio-One GmbH, 4550 Kremsmünster; Geno Technology Inc./G-Biosciences, 63132 St. Louis to list of significant subcontractors.

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Date	Reference Number	Action
23 July 2018	8995896	Change of EU representative from DIZG (Germany) to Emergo Europe (The Netherlands). 3 x STERIS subcontractor names updated to Isomedix Operations, Inc to align with ISO certification.
04 February 2019	7781547	Traceable to NB 0086.
Current	8954122	Addition of supplementary page. Scope extension to include 'sterile single use kits for processing of autologous adipose tissue'. Addition of Sequel Special Products and Sterigenics US, LLC (New York) to the list of significant subcontractors.