

EC Certificate - Production Quality Assurance

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

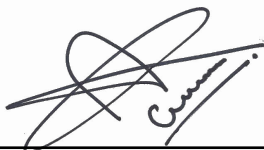
No. CE 569050
Issued To: **Musculoskeletal Transplant Foundation**
125 May Street
Edison
New Jersey
08837-9947
USA

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 2797):



Albert Roossien, Regulatory Lead

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

Date: **2019-02-04**

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

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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: **2019-02-04**
Issued To: **Musculoskeletal Transplant
Foundation
125 May Street
Edison
New Jersey
08837-9947
USA**

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

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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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USA**

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

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USA**

Subcontractor:

Service(s) supplied

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

**Assembly
Control of Sterilization
Packaging**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 569050**
 Date: **2019-02-04**
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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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Page 1 of 2

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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.
Current	7781547	Traceable to NB 0086.

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.