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 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: **2021-01-12** Expiry Date: **2024-05-26**

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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.

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.

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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	Lipografter system	n/a

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List of Significant Subcontractors

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

Certificate No:	**CE 569050**
Date:	**2021-01-12**
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**
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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Subcontractor:	**Service(s) supplied**
Sequel Special Products d.b.a Nissha Medical Technologies, Biomedical Innovations 1 Hillside Drive Wolcott Connecticut 06716 United States	**Manufacture**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance 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 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.
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.
11 December 2019	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.

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Date	Reference Number	Action
Current	3273914	Certificate renewal. Removal of sterile single use kits for separation of autologous blood plasma and fibrin from the scope of certification. Removal of CASCADE Autologous Platelet Systems from the supplementary information table. Removal of Geno Technology Inc./ G-Biosciences and Greiner Bio-One GmbH as crucial suppliers. Removal of Isomedix Operations, Inc (South Plainfield, New Jersey) as a subcontractor for ETO Sterilization. Removal of Isomedix Operations, Inc. (2500 Commerce Drive, Libertyville, Illinois) and Isomedix Operations, Inc. (1880 Industrial Drive, Libertyville, Illinois) as subcontractors for Gamma Sterilization. Removal of Millstone Medical Outsourcing LLC as a subcontractor for Assembly and Packaging. Removal of Riverside Medical Packaging Co Ltd as a subcontractor for Assembly, Control of Sterilization and Packaging. Change of approved subcontractor name from Sequel Special Products to Nissha Medical dba Sequel Special Products.

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