

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 792915 R001

**Manufacturer:** Musculoskeletal Transplant Foundation

**Address:**

125 May Street  
Edison  
New Jersey  
08837-9947  
USA

**Single Registration Number:** US-MF-000032713

**EU Authorised Representative:** Emergo Europe B.V.

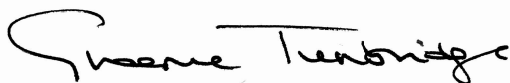
**Address:**

Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-01-28**

Current Issue Date: **2026-09-30**

Starting Validity Date: **2026-09-30**

Expiry Date: **2031-01-27**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

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### Device Schedule: Class IIa, Custom-made and other devices

| Device(s)          | Risk Classification |
|--------------------|---------------------|
| LipoGrafter System | Class IIa           |



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**MDR 792915 R001**

## Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

| Date       | Reference Number | Action                                                     |
|------------|------------------|------------------------------------------------------------|
| 2026-01-28 | 30001543         | Issued                                                     |
| Current    | 30788751         | Supplemented – Change of address of critical subcontractor |

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.  
A Member of the BSI Group of Companies.