



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Marizyme, Inc.
555 Heritage Drive
Suite 205
Jupiter
Florida
33458
USA

Holds Certificate Number:

MD 741109

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and final inspection of sterile solutions for the preservation, flushing and storage of tissues and organs.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-06-30

Latest Revision Date: 2021-06-30

Effective Date: 2021-06-30

Expiry Date: 2024-06-29

Page: 1 of 1



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

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 741108
Issued To: Marizyme, Inc.
555 Heritage Drive
Suite 205
Jupiter
Florida
33458
USA

In respect of:

Design, manufacture and final inspection of sterile solutions for the preservation, flushing and storage of tissues and organs.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2021-05-11**

Date: **2021-05-11**

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.



EC Certificate - Full Quality Assurance System

Supplementary Information to CE 741108

Issued To:

**Marizyme, Inc.
555 Heritage Drive
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33458
USA**

Device Code	Device Name	Intended purpose per IFU
Class IIa		
MD 0109	DuraGraft	---

First Issued: **2021-05-11**

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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.
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 741108**
Date: **2021-05-11**
Issued To: **Marizyme, Inc.**
555 Heritage Drive
Suite 205
Jupiter
Florida
33458
USA

Subcontractor:	Service(s) supplied
Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana CA (92705-5588) USA	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 741108**
Date: **2021-05-11**
Issued To: **Marizyme, Inc.
555 Heritage Drive
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Florida
33458
USA**

Date	Reference number	Action
Current	3339531	Issued.

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Page 1 of 1

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