

# **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## MIZUHO AMERICA, INC.

Main Site: 30057 Ahern Ave,

Union City, California, 94587, United States

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

## The management system is applicable to:

The design and development, manufacture, service of surgical trays, handheld surgical instruments for the area of cardiovascular, electrosurgical applications, ENT, neurology, orthopaedics and plastic surgery. Distribution of Original Equipment Manufacturer (OEM) surgical operating room tables, implants, monopolar and bipolar generators and their accessories and handheld surgical instruments for the area of cardiovascular, electrosurgical applications, ENT, neurology, orthopaedics and plastic surgery.

**Certificate Number:** 

0091502-01

**Initial Certification Date:** 

14 June 2019

**Date of Certification Decision:** 

3 June 2022

**Issuing Date:** 

13 June 2022

Valid Until:

13 June 2025





intertek

The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean

President

Intertek Testing Services NA Ltd., 1829, 32nd avenue, Lachine, QC, H8T 3J1, Canada







# Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that: HyperBranch Medical Technology, Inc 800-12 Capitola Drive Durham, NC 27713-4410 USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design and Development and Manufacture of Crosslinked Hydrogel Polymer Sealants and Related Delivery Systems.

Approved by: Kevin Mullaney Director of Certification

Registration Number: MD19.4678 Certification Granted: June 03, 2011 Effective Date: October 07, 2022 Expiry Date: October 04, 2025







## Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Collagen Matrix, Inc.

15 Thornton Road

Oakland **New Jersey** 07436 USA

Facility ID Number: F000134

Holds Certificate No: **MDSAP 689907** 

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full

Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

> Design and Development, Production and Distribution of Collagen- Based Medical Devices and Mineral-Based Medical Devices for Tissue Repair and Regeneration.

For and on behalf of BSI:

Original Registration Date: 2020-04-29

Graeme Tunbridge, Senior Vice President Medical Devices

Effective Date: 2023-03-17

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BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

Expiry Date: 2026-03-16

Certificate No: MDSAP 689907

07401 USA

Facility ID Number: F000134

Location Registered Activities

Collagen Matrix, Inc.

Design and Development, Production and Distribution of Collagen and Bone Mineral Based Medical Devices for Tissue Repair and Regeneration.

Oakland Repair
New Jersey
07436
USA

Facility ID Number: F000134

Collagen Matrix, Inc.

Production and Distribution of Collagen and Bone Mineral
Based Medical devices for Tissue Repair and Regeneration.

Allendale
New Jersey



Original Registration Date: 2020-04-29 Effective Date: 2023-03-17 Expiry Date: 2026-03-16

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### CERTIFICADO VALIDACIÓN ESTÁNDARES MÍNIMOS

### LA SUBGERENCIA NACIONAL DE PREVENCIÓN DE RIESGOS LABORALES DE LA ADMINISTRADORA DE RIESGOS LABORALES DE LA COMPAÑÍA DE SEGUROS BOLÍVAR S.A. - ARL DE SEGUROS BOLÍVAR

#### **CERTIFICA**

Que la empresa **EXEL MEDICAL SAS** identificada con **NIT 900127147** se encuentra afiliada a esta Administradora de Riesgos Laborales desde el **01** de **Diciembre** de **2022**, de igual forma, recibe asesoría y capacitación en Promoción y Prevención de Riesgos Laborales de acuerdo con las disposiciones legales vigentes por parte de esta Administradora de Riesgos y de acuerdo a los Estándares Mínimos SGSST definidos en la Resolución 0312/2019, validados por esta ARL el **15** de **Febrero** de **2023**, se encuentra en un avance del **98.25%** valoración **Aceptable** de implementación del sistema de gestión de seguridad y salud en el trabajo (SGSST) correspondientes al periodo **2022**.

Esta certificación se expide a solicitud del interesado a los **quince (15)** días del mes de **Febrero** de **2023**.

Atentamente,

Subgerencia Nacional de Prevención ARL Bolívar

Código transacción: SBSNDP-40996-0000001

YENNY E PAZ

ADO SUPERINTENDENCIA FINANCIERA DE COLOMBIA