

# Certificate of Registration

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

This is to certify that:

**Filmecc Co., Ltd.**  
1703 Wakita-cho, Moriyama-ku  
Nagoya-shi,  
Aichi  
463-0024  
Japan

Holds Certificate Number: MD 802631

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

Design and Development, Manufacture and Distribution of Diagnostic Catheters, Diagnostic Guidewires, Therapeutic Catheters, Therapeutic Guidewires, and the Peripheral Medical Devices for Diagnostic & Therapeutic Purposes

Transfer from TUV Rheinland  
Certificate Identity Number : SX 2159050-1

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-02-22

Latest Revision Date: 2024-02-22

Effective Date: 2024-02-22

Expiry Date: 2026-07-16

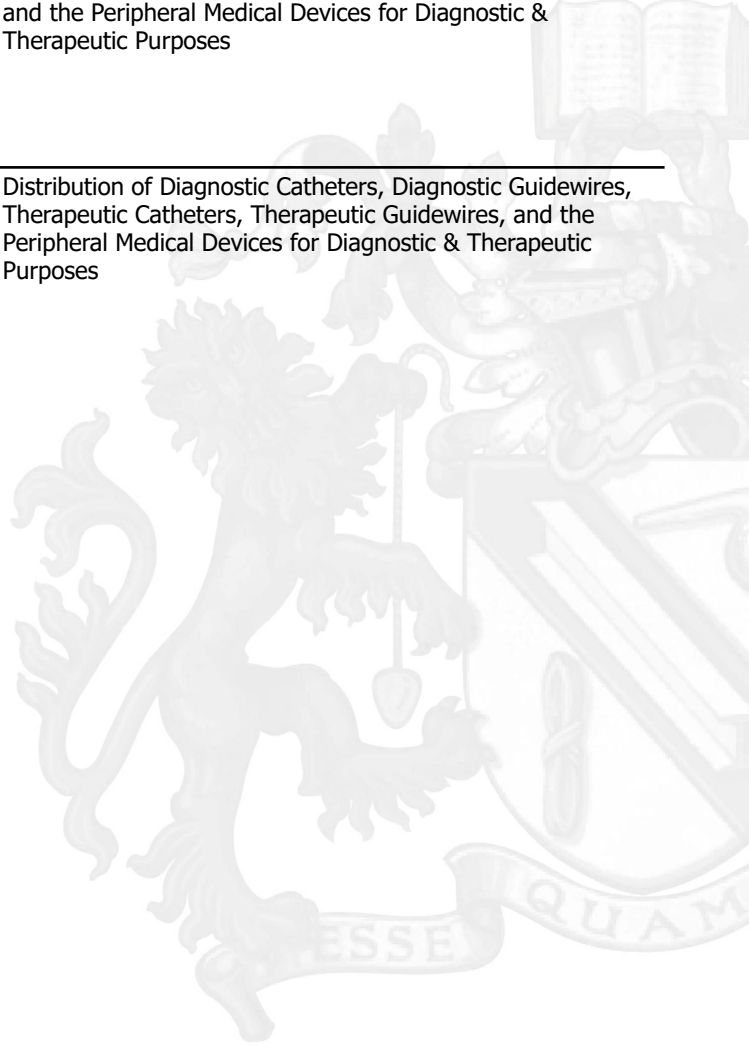
Page: 1 of 2



...making excellence a habit.™

Certificate No: MD 802631

Location	Registered Activities
Filmecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya-shi, Aichi 463-0024 Japan	Manufacture and Distribution of Diagnostic Catheters, Diagnostic Guidewires, Therapeutic Catheters, Therapeutic Guidewires, and the Peripheral Medical Devices for Diagnostic & Therapeutic Purposes
Filmecc Co., Ltd. Development Center 3-100 Akatsuki-cho Seto-shi, Aichi 489-0071 Japan	Design and Development of Diagnostic Catheters, Diagnostic Guidewires, Therapeutic Catheters, Therapeutic Guidewires, and the Peripheral Medical Devices for Diagnostic & Therapeutic Purposes
Filmecc Co., Ltd. Tokyo Office S-tec information Bldg., 1-24-1 Nishishinjuku, Shinjuku-ku, Tokyo 160-0023 Japan	Distribution of Diagnostic Catheters, Diagnostic Guidewires, Therapeutic Catheters, Therapeutic Guidewires, and the Peripheral Medical Devices for Diagnostic & Therapeutic Purposes



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Page: 2 of 2

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](http://www.bsigroup.com/ClientDirectory)

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