



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Filmecc Co., Ltd.

3-99 Akatsuki-cho,

Seto-shi, Aichi 489-0071 Japan フィルメック株式会社

〒489-0071 愛知県 瀬戸市

暁町3番地99

Holds Certificate No: MD 802631

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

Design and Development, Storage/Logistics and Distribution of Diagnostic and Therapeutic Catheters, Diagnostic and Therapeutic Guidewires and the Peripheral Medical Devices for Diagnostic and Therapeutic Purposes

検査用・処置用カテーテル、検査用・処置用ガイドワイヤー及び検査用・処置用周辺医療機器 の設計開発、保管/物流及び流通

Transfer from TUV Rheinland

Certificate Identity Number: SX 2159050-1

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-02-22

Latest Revision Date: 2025-09-01

Effective Date: 2024-02-22 Expiry Date: 2026-07-16

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...making excellence a habit."





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 <u>online</u>. Printed copies can be validated at www.bsi-global.com/ClientDirectory or Telephone 045-414-3022.