

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: COSMOTEC CO., LTD.
Twin View Ochanomizu Bldg. 1F
2-3-9 Hongo, Bunkyo-ku
Tokyo
113-0033
Japan

コスモテック株式会社
〒113-0033
東京都
文京区本郷2-3-9
ツインビューお茶の水ビル 1階

Holds Certificate No: MD 666767

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

Design & Development of Disease diagnosis program
Design & Development, Manufacturing and Sales of Implant Device, Surgery instruments and Perfusion Devices (Medical Devices Marketing Authorization Holder, Sales and Leasing License)
Manufacturing (Labeling) and Repairing of Perfusion Devices (Manufacturing License, Repairing License)
疾病診断用プログラムの設計・開発
埋込み医療機器、手術器具及び灌流装置の設計・開発、製造及び販売（製造販売業、販売業／貸与業）
灌流装置の製造（ラベリング）及び修理（製造業、修理業）

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2006-05-16

Latest Revision Date: 2023-08-07

Effective Date: 2021-05-16

Expiry Date: 2024-05-15



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Location	Registered Activities
<p>COSMOTEC CO., LTD. Twin View Ochanomizu Bldg. 1F 2-3-9 Hongo, Bunkyo-ku Tokyo 113-0033 Japan コスモテック株式会社 〒113-0033 東京都 文京区本郷2-3-9 ツインビューお茶の水ビル 1階</p>	<p>Design & Development of Disease diagnosis program Design & Development, Manufacturing and Sales of Implant Device, Surgery instruments and Perfusion Devices (Medical Devices Marketing Authorization Holder, Sales and Leasing License) Manufacturing (Labeling) and Repairing of Perfusion Devices (Manufacturing License, Repairing License) 疾病診断用プログラムの設計・開発 埋込み医療機器、手術器具及び灌流装置の設計・開発、製造及び販売（製造販売業、販売業／貸与業） 灌流装置の製造（ラベリング）及び修理（製造業、修理業）</p>
<p>COSMOTEC CO., LTD. Distribution Center Tokyo Danchi Warehouse Bldg A-1, 3-6-1, Heiwajima, Ohta-ku Tokyo 143-0006 Japan コスモテック株式会社 物流センター 〒143-0006 東京都 大田区平和島3-6-1 東京団地倉庫A-1棟 4階</p>	<p>Sales of Implant Device, Surgery instruments and Perfusion Devices (Sales and Leasing License) 埋込み医療機器、手術器具及び灌流装置の販売（販売業／貸与業）</p>
<p>COSMOTEC CO., LTD. Service Center Kowa Bldg-2, 3-17-11, Ueno, Taito-ku, Tokyo 110-0005 Japan コスモテック株式会社 サービスセンター 〒110-0005 東京都 台東区上野3-17-11 コーワビル2 1階</p>	<p>Manufacturing (Labeling), Repairing and Sales of Perfusion Devices (Manufacturing License, Repairing License and Sales and Leasing License) 灌流装置の製造（ラベリング）、修理及び販売（製造業、修理業、販売業／貸与業）</p>

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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 or telephone 045-414-3022

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