

Certificate of Registration

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

This is to certify that: Kitazato Corporation
100-10, Yanagishima,
Fuji,
Shizuoka
416-0932
Japan

株式会社北里コーポレーション
〒416-0932
静岡県
富士市
柳島100番地10

Holds Certificate No: MD 548540

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

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-10-22

Latest Revision Date: 2021-01-18

Effective Date: 2020-11-25

Expiry Date: 2023-11-24

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...making excellence a habit.™

Certificate No: MD 548540

Registered Scope:

Design, development, manufacture and aseptic processing of solutions (including mineral oil) for in-vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART)

Manufacture and sterilization of devices for in-vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART), catheter for fertilization treatment, biopsy needle for fertilization treatment.

Manufacture of pessaries

体外受精（IVF）及び生殖補助技術（ART）用溶液（ミネラルオイルを含む）の設計開発、製造及び無菌処理

体外受精（IVF）及び生殖補助技術（ART）用機器、不妊治療用カテーテル、不妊治療用生検針の製造及び滅菌

ペッサリーの製造

Original Registration Date: 2009-10-22

Latest Revision Date: 2021-01-18

Effective Date: 2020-11-25

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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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 548540

Location	Registered Activities
Kitazato Corporation 100-10, Yanagishima, Fuji, Shizuoka 416-0932 Japan 株式会社北里コーポレーション 〒416-0932 静岡県 富士市 柳島100番地10	Design, development, manufacture and aseptic processing of solutions (including mineral oil) for in-vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART) Manufacture and sterilization of devices for in-vitro Fertilization (IVF) and Assisted Reproductive Technologies (ART), catheter for fertilization treatment, biopsy needle for fertilization treatment. Manufacture of pessaries 体外受精 (IVF) 及び生殖補助技術 (ART) 用溶液 (ミネラルオイルを含む) の設計開発、製造及び無菌処理 体外受精 (IVF) 及び生殖補助技術 (ART) 用機器、不妊治療用カテーテル、不妊治療用生検針の製造及び滅菌 ペッサリーの製造
Kitazato Corporation Tokyo Office Shibakoen Building 1-1-8 Shibadaimon, Minato-ku, Tokyo 105-0012 Japan 株式会社北里コーポレーション 東京オフィス 〒105-0012 東京都 港区 芝大門一丁目1番8号 芝公園ビル	Manufacture of catheter and biopsy needle for fertilization treatment 不妊治療用カテーテル及び生検針の製造

Original Registration Date: 2009-10-22

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