

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: DENIS PHARMA K.K.
1-8-5 Ohsaku,
Sakura City,
Chiba
285-0802
Japan

DENISファーマ株式会社
〒285-0802
千葉県
佐倉市
大作1-8-5

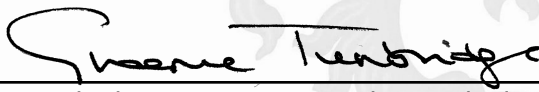
Holds Certificate No: MD 621224

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

The design, development, manufacture and sales of in vitro diagnostics reagents
(biochemistry, immunology and endocrinology)

体外診断用医薬品（生化学的検査用、免疫学的検査用、内分泌検査用）の設計・開発、製造
・販売

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-03-12

Latest Revision Date: 2024-02-06

Effective Date: 2024-03-12

Expiry Date: 2027-03-11

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Location

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Chiba
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Registered Activities

The design, development, manufacture and sales of in vitro diagnostics reagents (biochemistry, immunology and endocrinology)
体外診断用医薬品（生化学的検査用、免疫学的検査用、内分泌検査用）の設計・開発、製造・販売



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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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