

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Utsunomiya Seisaku Co.,Ltd.  
Tanimachi Bldg. 6F,  
2-6-4 Tanimachi,  
Chuo-ku, Osaka-shi  
Osaka  
540-0012  
Japan


宇都宮製作株式会社  
〒540-0012  
大阪府  
大阪市中央区  
谷町2-6-4  
谷町ビル6F

Holds Certificate No: MD 657988

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

Design, Development, Manufacture and Sales of Non-Latex Medical Exam Gloves  
Manufacture of Pulse Oximeter  
非天然ゴム製検査検診用手袋の設計・開発、製造、および販売  
機能検査オキシメータの製造

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-02-13

Latest Revision Date: 2023-01-20

Effective Date: 2023-02-13

Expiry Date: 2026-02-12



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Certificate No: MD 657988

Location

Utsunomiya Seisaku Co.,Ltd.  
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大阪府  
東大阪市  
本庄西1-5-1

Registered Activities

Sales of Non-Latex Medical Exam Gloves  
非天然ゴム製検査検診用手袋の販売

Design, Development, Manufacture and Sales of Non-Latex  
Medical Exam Gloves  
Manufacture of Pulse Oximeter  
非天然ゴム製検査検診用手袋の設計・開発、製造、および販  
売、機能検査オキシメータの製造

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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](http://www.bsigroup.com/ClientDirectory) or telephone 045-414-3022

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