

COPY

# ISO 13485

## Management System Certificate

Certificate Number : JQA-MD0100

Organization :

TAIYO NIPPON SANSO CORPORATION

MEDICAL UNIT, BIO-MEDICAL DIVISION

1-3-26 KOYAMA, SHINAGAWA-KU, TOKYO, JAPAN



ISO 13485



MS  
CM009

JQA certifies that the above organization operates the Quality Management System, within the scope of the Appendix attached, which has been assessed and found to comply with the requirements of,

ISO 13485:2016 / JIS Q 13485:2018

Registration Date : December 2, 2016

Last Renewal Date : March 1, 2022

Expiry Date : February 28, 2025

Feel free to contact JQA for the validity of this certificate.

A handwritten signature in black ink, reading 'N. Kobayashi'.

NORIAKI KOBAYASHI  
PRESIDENT

1-25 KANDASUDACHO, CHIYODA-KU, TOKYO, JAPAN

JAPAN QUALITY ASSURANCE ORGANIZATION

To be used in conjunction with attached Appendix.

The logo for JQA, consisting of the letters 'JQA' in a bold, blue, sans-serif font.

# ISO 13485

## Appendix



Certificate Number : JQA-MD0100

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Organization :

**TAIYO NIPPON SANSO CORPORATION**  
MEDICAL UNIT, BIO-MEDICAL DIVISION

Scope of Registration:

THE DESIGN / DEVELOPMENT, MANUFACTURE AND SALES SUPPORT OF THE FOLLOWING  
MEDICAL DEVICES

- 1) RESPIRATORY DEVICES
- 2) NON-ACTIVE INSTRUMENTS

ASSOCIATED ORGANIZATION:

- TAIYO NIPPON SANSO CORPORATION MEDICAL UNIT, BIO-MEDICAL DIVISION  
TECHNOLOGY DEPT. TECHNICAL DEVELOPMENT  
302-5 NAGANUMA-CHO, INAGE-KU, CHIBA-SHI, CHIBA, JAPAN  
[THE DESIGN / DEVELOPMENT OF THE PRODUCTS WITHIN THE SCOPE REGISTRATION]
- TAIYO NIPPON SANSO CORPORATION MEDICAL UNIT, BIO-MEDICAL DIVISION  
MEDICAL TECHNICAL SERVICE CENTER  
302-5 NAGANUMA-CHO, INAGE-KU, CHIBA-SHI, CHIBA, JAPAN  
[THE MANUFACTURE OF THE PRODUCTS WITHIN THE SCOPE REGISTRATION]
- TAIYO NIPPON SANSO CORPORATION MEDICAL UNIT,  
QUALITY ASSURANCE AND SAFETY MANAGEMENT DEPT.  
1-3-26 KOYAMA, SHINAGAWA-KU, TOKYO, JAPAN  
[THE OPERATION RELATED TO PHARMACEUTICAL AFFAIRS OF THE PRODUCTS WITHIN  
THE SCOPE REGISTRATION]

Registration Date : December 2, 2016  
Last Renewal Date : March 1, 2022

Expiry Date : February 28, 2025

Feel free to contact JQA for the validity of this certificate.

  
NORIAKI KOBAYASHI  
PRESIDENT

**JAPAN QUALITY ASSURANCE ORGANIZATION**

This Appendix is an integral part of the Certificate and should only  
be used in conjunction with the Certificate.

**JQA**