

COPY

ISO 13485

Management System Certificate

Certificate Number : JQA-MD0100

Organization :

TAIYO NIPPON SANZO CORPORATION

MEDICAL UNIT

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, 2025

Expiry Date : February 29, 2028

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

Handwritten signature of Hiroaki Ishii in black ink.

HIROAKI ISHII
PRESIDENT

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

JAPAN QUALITY ASSURANCE ORGANIZATION

To be used in conjunction with attached Appendix.

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

COPY

ISO 13485

Appendix

Certificate Number : JQA-MD0100

1 / 1



Organization :

TAIYO NIPPON SANZO CORPORATION
MEDICAL UNIT

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 SANZO CORPORATION MEDICAL UNIT, BIO-MEDICAL DIVISION
DEVELOPMENT AND ENGINEERING DEPARTMENT
302-5 NAGANUMA-CHO, INAGE-KU, CHIBA-SHI, CHIBA, JAPAN
[THE DESIGN / DEVELOPMENT OF THE PRODUCTS AND SALES SUPPORT WITHIN THE SCOPE
REGISTRATION]

· TAIYO NIPPON SANZO CORPORATION MEDICAL UNIT,
MEDICAL TECHNICAL SERVICE CENTER
302-5 NAGANUMA-CHO, INAGE-KU, CHIBA-SHI, CHIBA, JAPAN
[THE MANUFACTURE OF THE PRODUCTS WITHIN THE SCOPE REGISTRATION]

Registration Date : December 2, 2016

Last Renewal Date : March 1, 2025

Expiry Date : February 29, 2028

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

A handwritten signature in black ink, appearing to read 'H. Ishii', written over a horizontal line.

HIROAKI ISHII
PRESIDENT

JAPAN QUALITY ASSURANCE ORGANIZATION

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

The logo for Japan Quality Assurance Organization (JQA), consisting of the letters 'JQA' in a bold, blue, sans-serif font.