

ISO 13485

Management System Certificate



Certificate Number : JQA-MD0164

Organization :

SK MEDICAL ELECTRONICS CO., LTD.

NAGAHAMA FACTORY

305-1 SHICHIJO-CHO, NAGAHAMA-CITY, SHIGA, JAPAN



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 : July 30, 2021
Last Renewal Date : February 26, 2024

Expiry Date : February 25, 2027

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

A handwritten signature in black ink, reading 'H. Ishii'.

HIROAKI ISHII
PRESIDENT

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

JAPAN QUALITY ASSURANCE ORGANIZATION

To be used in conjunction with attached Appendix.



ISO 13485

Appendix



Certificate Number : JQA-MD0164

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Organization :

SK MEDICAL ELECTRONICS CO., LTD.
NAGAHAMA FACTORY

Scope of Registration:

DESIGN / DEVELOPMENT, MANUFACTURE AND OFFSITE REPAIR OF THE FOLLOWING MEDICAL DEVICES.

- PORCELAIN FURNACE FOR DENTAL LABORATORY
- CERAMICS HEATING PRESSURE MOLDING DEVICE FOR DENTAL LABORATORY
- CASTING FURNACE FOR DENTAL LABORATORY
- HIGH-FREQUENCY CASTING UNIT FOR DENTAL LABORATORY
- SMALL MOIST HEAT STERILIZER FOR UNWRAPPED GOODS
- SMALL WRAPPED GOODS MOIST HEAT STERILIZER
- BODY COMPOSITION ANALYZER
- CURING UNIT FOR DENTAL LABORATORY
- DENTAL POLISHING DEVICE
- ABRASIVE POINT FOR DENTAL LABORATORY

Transfer:

This registration has been TRANSFERRED from another Certification Body.
(Original Registration Date:May 2, 2005)

Registration Date : July 30, 2021
Last Renewal Date : February 26, 2024

Expiry Date : February 25, 2027

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Handwritten signature of Hiroaki Ishii in black ink.

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.