Current issue date: 8 October 2026
Expiry date: 11 October 2027
Certificate identity number: 10793556

Original approval(s):
ISO 13485 - 12 October 2018

Certificate of Approval

This is to certify that the Management System of:

Kanai Juyo Kogyo Co., Ltd.

4-1, Okuhata, Itami-shi, Hyogo-ken 664-0025, Japan

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 0071742

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:
Design,development andmanufacture ofnonsterile absorbable and non-absorbable internal fixation tool for medical use.
Manufacturing of fabric sheets for absorbable tissue spacers for radiation therapy, nonsterile metal wire and parts for disposable/nonactive medical devices.
Development of nonsterile implantable medical devices and ancillary tool for Spinal Fusion Surgery.
Design and development of surgical traction tool for medical use.

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Executive Vice President APAC

Issued by: LRQA Limited

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Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

Certificate Schedule

Location	Activities
Kanai Juyo Kogyo Co., Ltd. **Textile Machinery Factory** 4-1,Okuhata,Itami-shi,Hyogo-ken 664-0025, Japan	**ISO 13485:2016** Manufactureof nonsterile absorbable and non-absorbable internal fixation tool, and nonsterile metal wire and parts for disposable/nonactive medical devices.
Kanai Juyo Kogyo Co., Ltd. **Non-Woven Factory** 1-1,Kanai-cho,Takarazuka-shi, Hyogo-ken 665-0824, Japan	**ISO 13485:2016** Design anddevelopment of nonsterile absorbable and non-absorbable internal fixation tool, and surgical traction tool for medical use. Manufacturing of fabric sheets for absorbable tissue spacers for radiation therapy. Development of nonsterile implantable medical devices and ancillary tool for Spinal Fusion Surgery.
Tokusen Kogyo Co., Ltd. **Life Science Business Unit** 1081,Minamiyama,Sumiyoshi-cho, Ono-shi, Hyogo-ken 675-1361, Japan	**ISO 13485:2016** Manufactureofnonsterile metal wire and parts for disposable/nonactive medical devices.
Japan Fine Steel Co., Ltd. 1-19-1,Ishiide,Sanyo-Onoda-shi, Yamaguchi-ken, 756-0063, Japan	**ISO 13485:2016** Manufacturingofnonsterile metal wire for disposable/nonactive medical devices and nonsterile absorbable internal fixation tool for medical use.

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