

Current issue date: Expiry date: Certificate identity number: 3 March 2022 2 March 2025 10425724

Original approval(s): ISO 13485 - 23 January 2018

Certificate of Approval

This is to certify that the Management System of:

Sanko Medic Co., Ltd.

3-7-37, Nomura, Shunan-shi, Yamaguchi-ken 746-0022, Japan

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 00012107

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:

Manufacturing of nonsterile plastic parts for medical use, including disposable slide plates for clinical analyzers, plasma separating kits and parts for tracheotomy cannulas, processing of sterile implantable plastic sheet.

Yasushi Horikawa

Japan Operations Manager

Issued by: Lloyd's Register Quality Assurance (Shanghai) Co., Ltd.

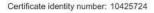
for and on behalf of: LRQA Limited

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Issued by: Lloyd's Register Quality Assurance (Shanghai) Co., Ltd., Room 1901-02, Ocean Tower, No. 550 Yan An Dong Road, Shanghai, 200001 for and on behalf of: LRQA

Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom





Certificate Schedule

Location

Activities

Tokuyama

3-7-37, Nomura, Shunan-shi, Yamaguchi-ken 746-0022, Japan

ISO 13485:2016

Manufacturing of nonsterile plastic parts for medical use, including plasma separating kits and parts for tracheotomy cannulas, processing of sterile implantable plastic sheet.

Moriyama

1-14-33, Shimonogo, Moriyama-shi, Shiga-ken 524-0013, Japan

ISO 13485:2016

Manufacturing of nonsterile plastic parts for medical use, including disposable slide plates for clinical analyzers.

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