

COPY

Certificate JP12/040341

The management system of

Nagashima Medical Instruments Co., Ltd.

Head Office 5-24-1 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 5 November 2021 until 5 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 5. Certified since 5 November 2012

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

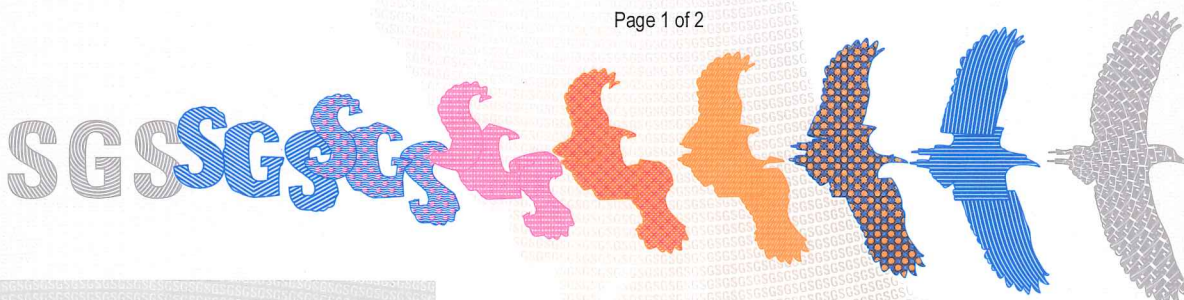


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Page 1 of 2



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Certificate JP12/040341, continued

Nagashima Medical Instruments Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016



Issue 5

Detailed scope

1. Design, manufacture and service of ENT units and chairs, nebulizers, suction devices, audiometers, eardrum anesthesia devices, eardrum drain tubes, phonation function examiners, laryngostroboscopes, operation microscopes, rigid endoscopes and externally power-supplied light sources, medical lighting devices, eye movement imaging devices and equilibrium function devices
2. Manufacture and service of surgical instruments

Additional facilities

Factory No.2 4-1-12 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

Factory No.3 5-24-17 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan



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Page 2 of 2