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

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

2. Manufacture and service of surgical instruments

This certificate is valid from 05 November 2024 until 05 November 2027 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 05 November 2012

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by Liz Moran

Business Manager

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Certificate JP12/040341, continued

Nagashima Medical Instruments Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016

Issue 7

Sites

Nagashima Medical Instruments Co., Ltd. Head Office 5-24-1 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

1. Management in support of Design, manufacture and service of ENT units and chairs, nebulizers, audiometers, eardrum anesthesia devices, eardrum drain tubes, phonation function examiners, laryngostroboscopes, operation microscopes and externally power-supplied light sources, medical lighting devices, eye movement imaging devices and equilibrium function devices

2. Management in support of manufacture and service of surgical instruments

Nagashima Medical Instruments Co., Ltd. Factory No.2 4-1-12 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

Design, manufacture and service of operation microscopes and externally power-supplied light sources, medical lighting devices, eye movement imaging devices and equilibrium function devices

Nagashima Medical Instruments Co., Ltd. Factory No.3 5-24-17 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

1. Design, manufacture and service of ENT units and chairs, nebulizers, audiometers, eardrum anesthesia devices, eardrum drain tubes, phonation function examiners, laryngostroboscopes

2. Manufacture and service of surgical instruments









