

Certificate JP05/040035

The management system of

Daiichi Medical Co., Ltd.

SGS

Head Office 2-27-16 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016/EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

1. Design, manufacture, installation and service of ENT units, nebulizers and endoscope washer disinfectors
2. Design, manufacture and service of ENT chairs, iontophoretic anaesthesia machines, general high frequency surgical equipment for ENT use, non-sterile reusable ENT surgical instruments, ENT optical equipment, orthopaedic surgical instruments, eye movement testing equipment, monitoring, treatment and examination equipment for dizziness
3. Design of software for electronystagmographs and eye movement testing equipment
4. Distribution and sales of active medical devices (non-implantable)

This certificate is valid from 08 February 2026 until 08 February 2029 and remains valid subject to satisfactory surveillance audits.

Issue 13. Certified since 08 February 2005

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

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ISO 13485:2016/EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 13

Sites

Daiichi Medical Co., Ltd. Head Office
2-27-16 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

1. Installation of ENT units, nebulizers and endoscope washer disinfectors
2. Design, manufacture and service of orthopaedic surgical instruments and eye movement testing equipment
3. Design of software for electronystagmographs and eye movement testing equipment
4. Distribution and sales of active medical devices (non-implantable)

Daiichi Medical Co., Ltd. Technical Center
2-39-11 Hongo, Bunkyo-ku, Tokyo, 113-0033 Japan

Design, manufacture and service of ENT units, nebulizers, endoscope washer disinfectors, ENT chairs, iontophoretic anaesthesia machines, general high frequency surgical equipment for ENT use, non-sterile reusable ENT surgical instruments, ENT optical equipment and monitoring, treatment and examination equipment for dizziness



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