Certificate JP25/00000076

The management system of



TKB Corporation / Tokibo Co., Ltd.

2-3-4, Higashiazabu, Minato-ku, Tokyo 106-8655, Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

- 1. Distribution of active medical device(non-implantable) and non-active medical device
- 2. Service of electrosurgical generator, operation table, medical endoscope, heated humidifier, CPAP, surgical instrument, ventilator, electrically-powered suction unit, electric body washer for medical use, ultrasound imaging system, non-active traction unit and oxygen concentrator
- 3. Service and installation of medical lighting device
- 4. Manufacturing of procedure packs for circuit sets of respiratory and anesthesia use, and ventilator filter

This certificate is valid from 11 March 2025 until 31 July 2025 and remains valid subject to satisfactory surveillance audits. Issue 1. Organization certified since 05 January 2006 and first certified by SGS on 11 March 2025. Certified activities performed by additional sites are listed on subsequent pages.

C. Moran

Authorised by Liz Moran Business Manager

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sqs.com











Certificate JP25/0000076, continued

TKB Corporation / Tokibo Co., Ltd.



ISO 13485:2016

EN ISO 13485:2016

Issue 1

Sites

TKB Corporation / Tokibo Co., Ltd.

2-3-4, Higashiazabu, Minato-ku, Tokyo 106-8655, Japan

- 1. Management in support of Distribution of active medical device(non-implantable) and non-active medical device
- 2. Management in support of Service of electrosurgical generator, operation table, medical endoscope, heated humidifier, CPAP, surgical instrument, ventilator, electrically-powered suction unit, electric body washer for medical use, ultrasound imaging system, non-active traction unit and oxygen concentrator
- 3. Management in support of Service and installation of medical lighting device
- 4. Management in support of Manufacturing of procedure packs for circuit sets of respiratory and anesthesia use, and ventilator filter

TKB Corporation / Tokibo Co., Ltd. Tokyo Front Terrace

2-3-14, Higashishinagawa, Shinagawa-ku, Tokyo 140-0002, Japan

- 1.Distribution of active medical device(non-implantable) and non-active medical device
- 2.Service of electrosurgical generator, operation table, medical endoscope, heated humidifier, CPAP, surgical instrument, ventilator, electrically-powered suction unit, electric body washer for medical use, ultrasound imaging system, non-active traction unit, oxygen concentrator and medical lighting device

TKB Corporation / Tokibo Co., Ltd. Oi Warehouse

1-4-3, Katsushima, Shinagawa-ku, Tokyo 140-0012, Japan

- 1.Distribution of active medical device(non-implantable) and non-active medical device
- 2.Service of electrosurgical generator, operation table, medical endoscope, heated humidifier, CPAP, surgical instrument, ventilator, electrically-powered suction unit, electric body washer for medical use, ultrasound imaging system, non-active traction unit and oxygen concentrator
- 3. Service and installation of medical lighting device
- 4. Manufacturing of procedure packs for circuit sets of respiratory and anesthesia use, and ventilator filter







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