



CERTIFICATE

TRYTECH Co., Ltd.

Shinagawa-ku, Tokyo, Japan

has implemented and maintains a Quality Management System for Medical Devices which fulfills Nemko's provisions for Management System Certification and the requirements of the following standard

ISO 13485:2016

The certificate covers the following activities:
Design and Development, Production, Labelling, Packing, Storage,
Distribution, Sales and Servicing of
Medical Device for Cardiac Surgery, Plastic Surgery, and Cardiology

Oslo, 2024-06-26

Helena Vogl

Nemko Scandinavia AS, Certification Department

First time issued

Expires

2017-06-07

2027-08-26







Certification document

Certification document no: 908367

Company name:

TRYTECH Co., Ltd.

Magnifique Minamiooi Bldg. 3F, 1-20-17, Minamiooi, Shinagawa-ku, Tokyo 140-0013, Japan

The certification also covers the following departments and activities:

Head Office Magnifique Minamiooi Bldg. 3F, 1-20-17, Minamiooi, Shinagawa-ku, Tokyo 140-0013, Japan	Design and Development, Production, Labelling, Packing, Storage, Distribution, Sales and Servicing of Medical Device for Cardiac Surgery, Plastic Surgery and Cardiology
Kansai Sales Office Bill Marujyo Bldg. 4F4A, 21-7, Takedakubo-cho, Fushimi-ku, Kyoto-shi, Kyoto 612-8411, Japan	Sales of Medical Device for Cardiac Surgery, Plastic Surgery and Cardiology

The certification according to ISO 13485:2016 was initially granted on 2017-06-07 in accordance with rules and regulations laid down by Nemko Scandinavia AS and Norwegian Accreditation (NA) as defined on the contracts last page.

The certification is granted under the condition that surveillance of the system is executed as a minimum once a year. The certificate expires 2027-08-26.

Oslo, 2024-06-26

Helena Vogl

Memko Scandinavia AS, Certification Department

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