



Certificate JP19/040498

The management system of

TOITU Co., Ltd.

Tokyo Head Office

1-5-10 Ebisu-Nishi, Shibuya-ku, Tokyo
150-0021 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 17 July 2020 until 17 July 2023
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 17 July 2008
and first certified by SGS Belgium on 31 October 2019
Recertification audit due before 02 July 2023

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

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Certification Manager

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Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015

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TOITU Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 2

Detailed scope

Design, development, manufacture, sales and servicing of medical devices for fetal monitor, Doppler fetal heartbeat detector, central monitor for pregnant, infant radiant warmer, photo-therapy for icterus and obstetric/gynecologic surgery

Additional facilities

Tsunashima Factory

**5-10-3 Tsunashima-Higashi, Kohoku-ku,
Yokohama-shi, Kanagawa-ken 223-0052 Japan**



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