Certificate JP14/040375



The management system of

ORTHOREBIRTH Co., Ltd.

Head office 10-1-203 Chigasaki-Chuo, Tsuzuki-ku, Yokohama-shi, Kanagawa pref., 224-0032 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 4 February 2019 until 4 February 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 November 2021

Issue 3. Certified since 22 April 2014

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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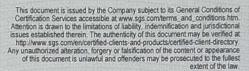
HC SGS 13485 2016 0118 M2

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Certificate JP14/040375, continued



ORTHOREBIRTH Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 3

Detailed scope

Design and manufacture of sterile resorbable and replacement type synthetic bone substitutes

Additional facilities

3-17-43 Chigasaki-Higashi, Tsuzuki-ku, Yokohama-shi, Kanagawa pref., 224-0033 Japan



Annex