



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Holds Certificate No:

Hakuzo Medical Corporation

2-4-9 Tokui-cho, Chuo-ku, Osaka-shi

Osaka 540-0025 Japan

MD 608111

ハクゾウメディカル株式会社

〒540-0025 大阪府

大阪市中央区 CERTIFIED TRUE COPY



Mr. Udomsak Suntithikavong

General Manager

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

> The design and development, manufacture of sterile/non-sterile gauze, sanitary/hygiene products for medical use and medical kit products.

The ethylene oxide sterilization service of medical devices.

滅菌及び未滅菌医療用ガーゼ、衛生材料及びメディカルキットの設計・開発及び製造 医療機器のエチレンオキサイド滅菌サービス

Gary C Stade

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-03-16

Latest Revision Date: 2020-02-28

Effective Date: 2020-03-16 Expiry Date: 2023-03-15

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...making excellence a habit."

Certificate No:

MD 608111

Location

Hakuzo Medical Corporation

2-4-9 Tokui-cho, Chuo-ku, Osaka-shi

Osaka 540-0025 Japan

〒540-0025 大阪府 大阪市中央区

ハクゾウメディカル株式会社

徳井町2-4-9 Hakuzo Medical Technos Corporation

Kumamoto Factory

205 Nagarekawa, Shichijo-machi,

Kikuchi-shi, Kumamoto 861-1367 Japan

ハクゾウメディカルテクノス株式会社

熊本工場 〒861-1367 熊本県 菊池市

七城町流川205

Registered Activities

The design and development of sterile/non-sterile gauze, sanitary/hygiene products for medical use and medical kit products.

The ethylene oxide sterilization service of medical devices. 滅菌及び未滅菌医療用ガーゼ、衛生材料及びメディカルキッ トの設計・開発

医療機器のエチレンオキサイド滅菌サービス

The manufacture of sterile/non-sterile gauze, sanitary/hygiene products for medical use and medical kit products.

The ethylene oxide sterilization service of medical devices. 滅菌及び未滅菌医療用ガーゼ、衛生材料及びメディカルキッ

医療機器のエチレンオキサイド滅菌サービス

Hakuzo Medical Technos Corporation

Fukushima Factory

2-2-1 Koyo, Soma-shi,

Fukushima

976-0005

Japan

ハクゾウメディカルテクノス株式会社

Original Registration Date: 2014-03-16 Latest Revision Date: 2020-02-28

福島工場

〒976-0005

福島県

相馬市

光陽2-2-1

The manufacture of sterile/non-sterile gauze, sanitary/hygiene products for medical use and medical kit

The ethylene oxide sterilization service of medical devices. 滅菌及び未滅菌医療用ガーゼ、衛生材料及びメディカルキッ トの製造

医療機器のエチレンオキサイド滅菌サービス

CERTIFIED TRUE COPY



Mr. Udomsak Suntithikavong General Manager

Effective Date: 2020-03-16 Expiry Date: 2023-03-15

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Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone 045-414-3022

Certificate No: MD 608111

Location

Hakuzo Medical Corporation Mihara Distribution Center 7 Tajii, Mihara-ku, Sakai-shi, Osaka 587-0012 Japan ハクゾウメディカル株式会社 美原物流センター 〒587-0012 大阪府 堺市美原区 多治井7番地

Registered Activities

The distribution of sterile/non-sterile gauze, sanitary/hygiene products for medical use and medical kit products. 滅菌及び未滅菌医療用ガーゼ、衛生材料及びメディカルキットの物流

CERTIFIED TRUE COPY



Mr. Udomsak Suntithikavong General Manager

Original Registration Date: 2014-03-16 Latest Revision Date: 2020-02-28 Effective Date: 2020-03-16 Expiry Date: 2023-03-15

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