



Certificate of Registration

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

This is to certify that:

ALCARE CO., LTD.

19F, Arcacentral Bldg.,

1-2-1 Kinshi, Sumida-ku, Tokyo 130-0013 Japan アルケア株式会社

〒130-0013 東京都 墨田区 錦糸1-2-1

アルカセントラル19階

Holds Certificate No:

MD 653032

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

Design, development and manufacture of stoma care/continence care products, medical stockings, skin care products, bandages, surgical tapes, braces, cast/splint, molding care products and measuring devices (rehabilitation training devices).

Design, development, manufacture and sterilization of dressings and drainage products.

ストーマケア・コンチネンスケア用品、弾性ストッキング、スキンケア用品、包帯、医療用テープ、装具・サポーター、キャスト・スプリント材、体位固定用品及び測定器(運動訓練装置)の設計、開発及び製造

ドレッシング材、ドレナージ用品の設計、開発、製造及び滅菌

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2005-09-02

Latest Revision Date: 2023-08-07

Effective Date: 2023-09-02 Expiry Date: 2026-09-01

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