

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM

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

Operates a QUALITY MANAGEMENT SYSTEM which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the activities detailed in the scope of registration.

上記組織が認証番号MD 653032を保有し、また下記認証登録範囲について ISO 13485:2016 & EN ISO 13485:2016 の要求事項に適合した品質マネジメントシステムを実施していることをここに証します。

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

ストーマケア・コンチネンスケア用品、ドレッシング材、ドレナージ用品、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、腰部固定帯、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

Is included as a location on Certificate number: **MD 653032**

And BSI location is: 0047599496-000

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2005-09-02

Effective Date: 2017-09-02

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