

Certificate of Registration

QUALITY MANAGEMENT SYSTEM

DENIS PHARMA K.K.
1-8-5 Ohsaku, Sakura City, Chiba 285-0802 Japan
DENISファーマ株式会社
〒285-0802千葉県佐倉市大作1-8-5

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

上記組織が認証登録番号MD 621224を保有し、また下記認証登録範囲について 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。

The manufacture and sales of in vitro diagnostics reagents
(biochemistry, immunology and endocrinology)
体外診断用医薬品（生化学的検査用、免疫学的検査用、内分泌検査用）の製造・販売

Is included as a location on Certificate number: **MD 621224**

And BSI location is: 0047536731-000

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-03-12

Latest Revision Date: 2021-09-01

Effective Date: 2021-03-12

Expiry Date: 2024-03-11



...making excellence a habit.™