

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM

Nissha Co., Ltd.  
Global Headquarters  
3 Hanai-cho, Mibu, Nakagyo-ku, Kyoto City, Kyoto Pref. 604-8551 Japan  
NISSHA株式会社  
本社  
〒604-8551 京都府京都市中京区壬生花井町3

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 710456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。

Incoming quality inspection, packaging and labeling, final storage of Single-use electrocardiograph electrode and Electrocardiograph cable or lead products and activities as a Marketing Authorization Holder under PMD Act.  
単回使用心電用電極、心電計ケーブル及びリードの受入検査、包装・表示、最終製品の保管及び薬機法に基づく製造販売業としての活動

Is included as a location on Certificate number: **MD 710456**

And BSI location is: 0047458463-032

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-10-29

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