

Certificate of Registration

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

This is to certify that:

CALCISCON AG
Aarbergstrasse 46
2503 Biel/Bienne
Switzerland

Holds Certificate Number:

MD 638801

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, manufacture and distribution of IVD test kits and related services for the assessment of calcification risk.

Gary E Slack

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-12-14

Latest Revision Date: 2021-12-08

Effective Date: 2021-12-14

Expiry Date: 2024-12-13

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