

Certificate of Registration

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

This is to certify that:

VIVOLTA
Van Dijklaan 6
Waalre
5581 WG
The Netherlands

Holds Certificate Number:

MD 741956

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

The design, development, manufacturing and packaging of non-sterile fibre-based scaffolds for use in medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-08-12

Latest Revision Date: 2024-07-29

Effective Date: 2024-08-12

Expiry Date: 2027-08-11

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