

Certificate of Registration

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

This is to certify that:

Hightech Contract Manufacturing Medical
Kerkenbos 10-113
Nijmegen
6546 BJ
The Netherlands

Holds Certificate Number:

MD 650932

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

Contract manufacture and packaging of sterile tissue-regenerative medical devices.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-04-19

Latest Revision Date: 2025-03-27

Effective Date: 2025-04-19

Expiry Date: 2028-04-18

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