

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Harland Medical Systems
7418 Washington Avenue S.
Eden Prairie
Minnesota
55344
USA

Holds Certificate Number: **FM 526278**

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

Lubricious coating and primer to treat surface for the coating solutions, Design, Manufacturing, Testing Services and Contract Manufacturing of Medical Device applications. Design Manufacturing Installation and Service of Automated Production applications. Design, Manufacturing, Installation and Service of Automated Production and Test Systems for lubricious coating and primer to treat surface for the coating solutions of medical device applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2008-01-14

Latest Revision Date: 2023-01-09

Effective Date: 2023-01-14

Expiry Date: 2026-01-13

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Certificate No: FM 526278

Location	Registered Activities
Harland Medical Systems 7418 Washington Avenue S. Eden Prairie Minnesota 55344 USA	Surface modification, Design, Manufacturing, Testing Services and Contract Manufacturing of Medical Devices. Design, Manufacturing, Installation and Service of Automated Production and Test Systems for Surface Modification.
Harland Medical Systems Europe Unit 1 Cherrywood Business Park Little Island Cork T45 XP70 Ireland	Surface Modification, Design, Manufacturing, Testing Services and Contract Manufacturing of Medical Devices, Installation and Service of Automated Production and Test Systems for Surface Modification.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

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Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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