

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 Global Regulatory & Quality

Original Registration Date: 2008-01-14

Latest Revision Date: 2025-08-06

Effective Date: 2023-01-14

Expiry Date: 2026-01-13

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BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

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.
Harland Medical Systems Costa Rica, SRL Grupo Desarrollador De Parques Industriales Sociedad Anonima Alajuela San Jose Costa Rica	Contract service provider of coating and primer surface treatment solutions and coating services for medical device applications, including the installation and servicing of automated coating equipment and coatings test systems.

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