

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: 2026-01-08

Effective Date: 2026-01-14

Expiry Date: 2029-01-13

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

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

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

Certificate No: FM 526278

Location

Registered Activities

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

Contract service provider of coating and primer surface treatment solutions for medical device applications including the design and modification of surfaces for medical device applications. Design, Manufacturing, and Installation and servicing of automated coating equipment and surface modification test systems.

Harland Medical Systems Europe
Unit 1 Cherrywood Business Park
Little Island
Cork
T45 XP70
Ireland

Manufacture of lubricious coating and primer surface treatment processes for medical device applications. Installation and servicing of automated coating equipment and coating test systems. Testing services for surface properties of medical devices.

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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