By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Mesa Laboratories
12100 West 6th Avenue
Lakewood
Colorado
80228
USA

Holds Certificate Number: FM 78646

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

The design, development, manufacture and distribution of measuring and test instruments used in hemodialysis therapy. These devices include systems that reprocess and test multiple-use dialyzers for safe and effective reuse, as well as dialysate meters and reference standards used to test and/or calibrate dialysis delivery systems. The design, development, manufacture and distribution of incubators for biological indicators for use in validation and monitoring of sterilization systems. The manufacture, service, calibration and distribution of precision ambient air monitoring and flow calibration instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-08-30
Effective Date: 2024-03-20
Latest Revision Date: 2024-01-10
Expiry Date: 2027-03-19

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
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Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.