

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 No:

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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-08-30

Latest Revision Date: 2018-12-06

Effective Date: 2019-01-01

Expiry Date: 2021-03-19

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