



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Promega Corporation

2800 Woods Hollow Road

Madison Wisconsin 53711-5399

**USA** 

Facility ID Number: F005139

Holds Certificate No: MDSAP 732547

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture and servicing of reagents, reagent support systems and instrumentation for the medical device and in-vitro diagnostic markets.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-08-11 Effective Date: 2024-08-09 Expiry Date: 2027-08-08

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...making excellence a habit."



Certificate No: MDSAP 732547

Location Registered Activities Promega Corporation Fermentation and Manufacturing. 2800 Woods Hollow Road Madison Wisconsin 53711-5399 USA Facility ID Number: F005139 Promega Corporation Receiving, Manufacturing, Dispensing, Packaging, Shipping, Warehouse. 2780 Woods Hollow Drive Madison Wisconsin 53711 USA Facility ID Number: F005139 **Promega Corporation** Receiving, Manufacturing, Packaging, Shipping, Warehouse. 5455 Nobel Drive Madison Wisconsin 53711 **USA** Facility ID Number: F005139 Receiving, Manufacturing, Dispensing, Packaging, Shipping, Promega Corporation Warehouse. 5445 East Cheryl Parkway Madison Wisconsin 53711 USA Facility ID Number: F005139 **Promega Corporation** Receiving, Manufacturing, Warehouse.

Facility ID Number: F005139

2617 Progress Rd

Madison Wisconsin 53716 USA

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Certificate No: **MDSAP 732547** 

Location Registered Activities

**Promega Corporation** 

5500 East Cheryl Parkway Madison Wisconsin 53711 **USA** 

Facility ID Number: F005139

Promega Corporation Engineering & Operations Support.

2798 South Fish Hatchery Road Madison Wisconsin 53711 USA

Facility ID Number: F005139

**Promega Corporation** Research and Development, Manufacturing.

Administrative Offices.

5430 East Cheryl Parkway Madison Wisconsin 53711 **USA** 

Facility ID Number: F005139

Engineering & Operations Support. Promega Corporation

5511 Bjorksten Place Madison Wisconsin 53711

USA Facility ID Number: F005139

Research and Development, Receiving, Manufacturing, **Promega Corporation** 

5500/5510 Nobel Drive Madison Wisconsin 53711 USA

Facility ID Number: F005139

Packaging, Warehouse, Instrument Servicing.

Original Registration Date: 2021-08-11 Effective Date: 2024-08-09 Expiry Date: 2027-08-08

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Certificate No: MDSAP 732547

Location Registered Activities

Promega Corporation 3075 Sub-Zero Pkwy

Fitchburg Wisconsin 53719 USA

Facility ID Number: F005139

Promega Corporation 2800 Fish Hatchery Road

Madison Wisconsin 53711 USA

Facility ID Number: F005139

Receiving, Manufacturing, Dispensing, Packaging, Shipping, Warehouse.

Manufacturing



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