



America

# CERTIFICATE

No. QS2 123049 0001 Rev. 00

**Certificate Holder:** DirectMed, Inc  
98 Pratt Oval  
Glen Cove NY 11542  
USA

**Certification Mark:**



**Scope of Certificate:**

**Design, Development, and Provision of Production and ETO Sterilization Services of Sterile Intravascular Administration and Extension Sets for Sterile Fluid Delivery with or without Flow Control Features**

**Provision of Production and ETO Sterilization Services of Irrigation-Suction Kit and Suction Tubing for Single Use Irrigation and Suction**

**Distribution of Plastic Components including Injection Sites, Kit Accessories, IV Spikes, Tubing, Luers, Enfit System, Stopcocks, Bag Ports, Syringes, Caps, Tubing Clamps, Chambers, Valves, Connectors, Filters and Flow Regulators for Medical Devices**

**Standard:** ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** 72194877

**Effective Date:** 2024-04-10

**Expiry Date:** 2027-04-09

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( Renee Walker )  
Director, US Certification Body, MHS