

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo Cardiovascular Systems
Corporation
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Holds Certificate No:

FM 584812

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

Design and Development, Manufacturing and Distribution of Blood Oxygenators, Centrifugal Pumps, Arterial Filters, Cardioplegia Delivery Sets, Cardiovascular Procedure Kits, Pressure Relief Valves, CDI Cuvettes, CDI Shunt Sensors, CDI Calibration Gases, Blood Reservoirs and Endoscopic Vessel Harvesting Systems, On and Off Pump Coronary Artery Bypass Graft Instruments/Devices and Accessories.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2012-05-08

Latest Revision Date: 2018-10-15

Effective Date: 2018-10-15

Expiry Date: 2021-10-14



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