By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Allmed Middle East
2nd Industrial Zone No. 72
6th October City
Giza 12541
Egypt

Facility ID Number: F003382

Holds Certificate No: **MDSAP 712077**

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

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
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

Design, development, manufacture (including private labelling), distribution of sterile arterial/venous bloodlines, polysulfone and polyethersulfone hollow fiber hemodialzyers, hemofilter hollow fiber hemofilter, fistula needle, infusion and transfusion sets, dry bicarbonate cartridges, dry bicarbonate bags, fluidic concentrated hemodialysis solutions, dialysis equipment cleaning cartridges, and bacterial and endotoxin retention filter.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-04-30 Effective Date: 2025-10-05 Expiry Date: 2028-10-04

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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