



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Tristel Solutions Limited

Unit 1B Lynx Business Park

Fordham Road Snailwell CB8 7NY

United Kingdom

Facility ID Number: F002715

Holds Certificate No: MDSAP 703572

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; 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 distribution of disinfecting, cleansing and sterile wipes, disinfectant solutions, dosing and control systems and washing and disinfection systems. The installation and service of chlorine dioxide generators, dosing and control systems and washing and disinfection systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-06-19 Effective Date: 2022-06-19 Expiry Date: 2025-06-18

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."