

Certificate of Approval

This is to certify that the Management System of:
Medical Wire & Equipment Co. (Bath) Ltd

Potley Lane, Corsham, SN13 9RT, United Kingdom
MDSAP Facility Identifier: F003637

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 –
Production Quality Assurance Procedure

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68
PMD Act

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820



Chris Koci – Business Director, Certification
Issued By: Lloyd's Register Quality Assurance, Inc.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Certificate approval number: LRQ0939857/D

Original approval:

Effective date: 2019 June 14

MDSAP/ISO 13485 – 2019 June 14

Expiry date: 2022 June 13

Certificate issue number: 10200774

The scope of approval is shown on the next page and bears the same certificate identity number

Approval Number: MDSAP – 0079103



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.
Issued by: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom for and on behalf of: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States

Certificate of Approval

The scope of this approval is applicable to:

Design, development and manufacture of sterile collection swabs and associated devices for use in medical microbiology. Design and manufacture of sterile amniotic fluid collection devices for use in obstetrics and gynaecology. Design, development and manufacture of loops, media, rapid test strips, microrings and sample containers for patient sample collection and diagnostic applications.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.

Issued by: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom for and on behalf of: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States