

Certificate GB23/00000374

The quality management system of

Medical Wire & Equipment Co (Bath) Ltd

SGS

Potley Lane Corsham Wiltshire SN13 9RT United Kingdom
Facility number: F007109

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

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 media for patient sample collection and diagnostic applications.

Manufacture of loops for diagnostic applications

This certificate is valid from Effective date 2023-10-26 until Expiry date 2026-10-25 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 2023-10-26

Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by

Lynn Henderson

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Certificate GB23/00000374, continued

Medical Wire & Equipment Co (Bath) Ltd

MDSAP (ISO 13485:2016)

SGS

Issue 1
Sites
Medical Wire & Equipment Co (Bath) Ltd Potley Lane Corsham Wiltshire SN13 9RT United Kingdom
Campuses
Hopton Industrial Estate London Rd Devizes SN10 2EU United Kingdom
Unit 3 Leafield Industrial Estate Corsham Wiltshire SN13 9SS United Kingdom
Unit 21 Leafield Industrial Estate Corsham Wiltshire SN13 9SW United Kingdom



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