Medical Device Production Quality Assurance System
Certificate GB22/00000334

The management system of

Medical Wire & Equipment Co (Bath) Ltd

Unit 29 Potley Lane Corsham Wiltshire SN13 9RT United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 04 December 2024 until 24 November 2029 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 02 July 1997

L. Henderson

Authorised by
Lynn Henderson

SGS United Kingdom Ltd Approved Body 0120
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Medical Device Production Quality Assurance System
Certificate GB22/00000334, continued

Medical Wire & Equipment Co (Bath) Ltd

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 4

Surgically invasive sterile collection swabs used for patient sample collection. Includes swabs supplied as part of a sample collection kit: Rayon, Cotton, Foam, Polyester Fibre branded as Hydraflock® and Purflock® swabs with brand names Transwab®, Transtube®, Sigma Transwab®

Sterility aspects only – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Invasive Body Orifice and Non Invasive Body Sterile Collection Swabs used for patient sample collection. Includes collection swabs supplied as part of a sample collection Kit:
Cotton, Rayon, Dacron, Nylon, Foam - Polyester Fibre branded as HydraFlock® and Purflock® swabs with brand names Sigma GBS™, Sigma TSB™, Sigma Virocult®, Sigma VCM™, Fecal Transwab™, Dryswab™, Cytotak™, Sigma Swab®.
Hospiswab™ Sterile collection swab for patient sample collection on intact skin only.
Amnicator™ - Amniotic fluid leak detection device.

Where the above scope includes class IIb or class III medical device(s), a valid Type Examination Certificate according to Annex III [as modified by Part 2 of Schedule 2A to The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/240496
Previous certificate number: N/A
Change in between this certificate and previous one: change of addresses

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

Medical Device Production Quality Assurance System
Certificate GB22/00000334, continued

Medical Wire & Equipment Co (Bath) Ltd

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 4

Sites

Medical Wire & Equipment Co (Bath) Ltd
Unit 29 Potley Lane Corsham Wiltshire SN13 9RT United Kingdom

Medical Wire & Equipment Co (Bath) Ltd
Unit 8/9 Hopton, Industrial Estate, London Rd, Devizes, SN10 2EU, United Kingdom

Medical Wire & Equipment Co (Bath) Ltd
Unit 3 Leafield Industrial Estate Corsham Wiltshire SN13 9SS United Kingdom

Medical Wire & Equipment Co (Bath) Ltd
Unit 21 Leafield Site Leafield Industrial Estate, Corsham, Wiltshire, SN13 9SW, United Kingdom

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.