Sygnatura akt: Podpisał
Dokument podpisany przez Patrycja Małgorzata
Data: 2021.[illegible] 10:31:13 CET

EC Certificate Production Quality Assurance System: Certificate GB20/965308

The management system of

Medical Wire & Equipment Co (Bath)Ltd

Potley Lane, Corsham, Wiltshire, SN13 9RT, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 February 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 02 July 1997
and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC/ 240496

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Pieter Weterings
Certification Manager

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Medical Wire & Equipment Co (Bath)Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 1

Detailed scope:

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 EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

Hopton Industrial Estate, London Rd, Devizes, SN10 2EU, UK

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