EC Certificate Full Quality Assurance System: Certificate GB19/964726

The management system of

Owen Mumford Limited

Brook Hill, Woodstock, Oxfordshire, OX20 1TU, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 16 December 2019 until 24 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 31 March 1995
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 04459

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

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Owen Mumford Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Single use sterile capillary blood sampling lancets and contact activated safety lancets.

Sterile pen needles and sterile safety pen needles for use with pen injectors for drug delivery.

Non-sterile auto-injection devices and pen-injectors for drug delivery.

Class I Sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Sterile, single use esthesiometers for the use of detecting loss of sensation and nerve damage.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Primsdown Industrial Estate, Worcester Road, Chipping Norton, Oxfordshire, OX7 5XP, UK