

EC Certificate Full Quality Assurance System: GB95/7927.00

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 06 February 2017 until 25 March 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 25 March 2019

Issue 18. Certified since 31 March 1995

Certification is based on reports numbered GB/PC 04459

Multiple certificates have been issued for this scope

The main certificate is numbered GB95/7927.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd

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SGS CE 02 0315 M2

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Owen Mumford Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 18

Detailed scope

Sterile capillary blood lancets for blood sampling and sterile pen needles for use with pen-injectors for drug delivery devices.

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

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**

**Units 12a and 22 Worcester Road, Chipping Norton,
Oxfordshire, OX7 5XP, UK**