

Certificate Number GB19/964163

The management system of

Owen Mumford Limited

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

Dun & Bradstreet D-U-N-S identification number: 21-726-6915

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)
– Full Quality Assurance Procedure [including design]

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

United States:
21 CFR 820/ 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-10-09 until Expiry Date: 2022-10-08
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-02-21
Issue 1. Certified since 2019-10-09

Authorised by J Hall
Business Manager



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MDSAP M2

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Owen Mumford Limited

MDSAP (ISO 13485:2016)



Detailed scope

Design, development, manufacture and distribution of:

Single use sterile capillary blood sampling lancets, contact activated safety lancets, and non-sterile reusable device for insertion of sterile 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.

Sterile, single-use and non-sterile reusable esthesiometers, vaginal dilators, vacuum devices for erectile dysfunction, non-sterile reusable device for administration of eye drops.

Additional facilities

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

