

Certificate GB19/964163

SGS

The quality management system of

Owen Mumford Limited

Brook Hill Woodstock Oxfordshire OX20 1TU United Kingdom

Facility number: F003805

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System;

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

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68; PMD Act

United States: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals;

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing; 21 CFR Part 820 - Quality System Regulation;

For the following activities

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.

This certificate is valid from Effective date 2022-10-07 until Expiry date 2025-04-24 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2019-10-09

Certified activities performed by additional sites listed on subsequent pages.



Authorised by

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Head of NB1639

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com



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Owen Mumford Limited

MDSAP (ISO 13485:2016)

Issue 2
Sites
Owen Mumford Limited Brook Hill Woodstock Oxfordshire OX20 1TU United Kingdom
Owen Mumford Limited Primsdown Industrial Estate Worcester Road Chipping Norton Oxfordshire OX7 5XP United Kingdom



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