

Certificate GB19/964210

The quality management system of

# Haag Streit UK Ltd

SGS

Unit C Woodside Industrial Estate Dunmow Road Bishop's Stortford Hertfordshire CM23 5RG

United Kingdom

Facility number: F003821

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 (SOR/98-282) Part 1 - General

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ministerial Ordinance No. 60 (2021), Japan PMD Act (as applicable)

USA: 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, manufacture and service of ophthalmics slit lamps and applanation tonometers.

Design and manufacture of ophthalmic sterile tonosafe disposable prisms and sterile schirmer tear test assessment strips.

This certificate is valid from Effective date 2025-07-06 until Expiry date 2028-07-06 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 2019-10-15

Certified activities performed by additional sites are listed on subsequent pages.

*L. Henderson*

Authorised by

Lynn Henderson

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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](http://www.SGS.com).



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Certificate GB19/964210, continued

# Haag Streit UK Ltd

# SGS

## MDSAP (ISO 13485:2016)

Issue 6

### Sites

Campus:

Suites 2 & 4 2 Woodside Industrial Estate Dunmow Road Bishop's Stortford Hertfordshire CM23 5RG  
United Kingdom



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