Certificate GB19/964210

The quality management system of

Haag Streit UK Ltd

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

Facility Identification 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
Brazil: RDC ANVISA n. 665/2022- Good Manufacturing Practices, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
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 2024-04-11 until Expiry date 2025-07-06 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 2019-10-15
Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by
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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.

Haag Streit UK Ltd

MDSAP (ISO 13485:2016)

Issue 4

Sites
Haag Streit UK Ltd

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

Campus
Haag Streit UK Ltd

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