Medical Device Production Quality Assurance System Certificate GB22/0000251



The management system of

Haag Streit UK Ltd

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

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 06 November 2024 until 06 July 2027 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 13 March 1995

2. Henderson

Authorised by Lynn Henderson

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Medical Device Production Quality Assurance System Certificate GB22/00000251, continued



Haag Streit UK Ltd

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 5

Annex V Metrological aspects only – Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements:

Pinhole Occluder

Annex V Sterility aspects only – Restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements:

Schirmer tear test.

Where the above scope includes class IIb or class III medical device(s), a valid Type Examination Certificate according to Annex III [as modified by Part 2 of Schedule 2A to The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/230587

Previous certificate number: N/A

Change in between this certificate and previous one: Removal of RAF Binocular Gauge from the scope



Haag Streit UK Ltd



Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 5

Sites

Haag Streit UK Ltd

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

Haag Streit UK Limited

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



