

Medical Device Full Quality Assurance System Certificate
GB23/00000282



The management system of

Altomed Limited

Unit 2 Witney Way Boldon Business Park Tyne and Wear NE35 9PE United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [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 26 March 2024 until 25 October 2028 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 16 July 2023

Authorised by
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Altomed Limited

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Sterile Symblepharon rings to prevent the eyelid from adhering to the eyeball.

Sterile Ophthalmic conformers inserted temporarily between the eyeball and eyelid to maintain space & structure in the orbital cavity and prevent closure or adhesions during the healing process following eye surgery.

Sterile Ocular tumour markers placed over a tumour that is inside the eye to help determine optimal positioning of an eye brachytherapy plaque.

Sterile Orbital Implants sutured to the sclera to prevent collapse of the globe during difficult intraocular operations.

Sterile Platinum segment eyelid weight for the treatment of lagophthalmos.

Sterile Implantable tubes as a tear drainage treatment from the front surface of the eye for lacrimal canalicular pathologies in functional or obstructive epiphora.

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certificate is based on reports numbered GB/PC/09704

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

