

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

AJL Ophthalmic SA
Parque Tecnológico de Álava
Ferdinand Zeppelin 1
Miñano
Alava
01510
Spain

Holds Certificate Number:

MD 685631

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacturing, sterilization and distribution of sterile ophthalmic medical devices (intraocular lenses, intracapsular rings, intracorneal rings, scleral implants, palpebral implants, silicone oil, and iris expander), sterile ophthalmic solutions (viscoelastic and dye solutions), sterile oculoplasty products, sterile craniomaxillofacial implants, and non-sterile fiberoptic intubation airway.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-03-12

Latest Revision Date: 2019-03-12

Effective Date: 2019-03-12

Expiry Date: 2022-03-11

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