America

CERTIFICATE

No. QS6 18 05 86611 013

Certificate Holder: VISIA IMAGING S.r.l.
Via Martiri della Libertà 95/e
52027 San Giovanni Valdarno (AR)
ITALY

Certification Mark:

Scope of Certificate: Design and Production of Medical Electrical Equipments and Software in Ophthalmology and In Vitro Diagnostic Areas: Integrated Device Ocular Biometers and Corneal Analyzers, Corneal Topographers, Digital Video Cameras for Slit Lamp, LCD Chart Projectors, Integrated Controllers for Computerized Phoropters, Scanning Devices for Autoimmunity, Slide Scanners for Digital Pathology (Bright-Field and/or Fluorescence Microscopy Solutions), Fully Automated IFA Slide Processors

Standard(s): ISO 13485:2016

Regulatory Authority: Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 44-766-8039
Effective Date: 2018-05-25
Expiry Date: 2021-05-24

Manuel Bradaric
MHS Certification Manager

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Audit/Certification Criteria

Australia

- **Therapeutic Goods (Medical Devices) Regulations 2002**
- **Schedule 3, Part 1**

Brazil

- **RDC ANVISA n. 16/2013**
- **RDC ANVISA n. 23/2012**
- **RDC ANVISA n. 67/2009**

Canada

- **Medical Device Regulations SOR/98-282, Part 1**

United States

- **21 CFR Part 803**
- **21 CFR Part 806**
- **21 CFR Part 807**
- **21 CFR Part 820**

Japan

- **MHLW Ministerial Ordinance No.169, 2004**

Effective Date: **2018-05-25**
Expiry Date: **2021-05-24**

Manuel Bradaric
Certification Manager MHS