



America

CERTIFICATE

No. QS6 18 07 70221 012

Certificate Holder: CenterVue S.p.A.
Via San Marco, 9h
35129 Padova
ITALY

Certification Mark:



Scope of Certificate: Design, Production, Service and Distribution
of Automatic Perimeters and Ophthalmoscope

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: 33-870-2316
Effective Date: 2018-07-08
Expiry Date: 2021-07-07

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

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Manuel Bradaric
Certification Manager MHS

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