



America

CERTIFICATE

No. QS6 103953 0001 Rev. 00

Certificate Holder: **NTC S.r.l.**
Via Dei Gracchi 35
20146 MILANO MI
ITALY

Certification Mark:



Scope of Certificate: **Design, Development and Manufacture of Solutions, Ointments and Gels for Ophthalmology**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Brazil ANVISA, Health Canada. 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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **51-687-5155**

Effective Date: **2020-07-17**

Expiry Date: **2023-07-16**

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Date of Issue: 2020-07-22

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Brazil

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

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies):


NTC S.r.l.
Via Dei Gracchi 35, 20146 MILANO MI, ITALY

Facility Scopes:

Design, Development and Manufacture of Solutions,
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