



America

# CERTIFICATE

No. QS6 18 06 95187 005

**Certificate Holder:** Statcorp Medical  
35301 SE Center Street  
Snoqualmie WA 98065  
USA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Infusion Cuffs and Blood Pressure Cuffs

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

**Regulatory Authority:** Australia TGA, Health Canada, USA FDA.  
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:** 03-894-2055  
**Effective Date:** 2018-06-03  
**Expiry Date:** 2021-05-20

Manuel Bradaric  
MHS Certification Manager



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# CERTIFICATE

No. QS6 18 06 91587 005

## Audit/Certification Criteria

### Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1
- Schedule 3, Part 4

### 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
- 21 CFR Part 821

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Manuel Bradaric  
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