



America

CERTIFICATE

No. QS6 095187 0009 Rev. 02

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(ies): **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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_095187_0009_Rev.02

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

REPs Facility ID: **F001355**
Report No.: **72196366**
Effective Date: **2024-05-19**
Expiry Date: **2027-05-18**

Page 1 of 2

Date of Issue: 2024-04-17

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
-Schedule 3, Part 4 – Production Quality Assurance Procedure

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):

Statcorp Medical

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Facility Scopes:

Design and Development, Production and Distribution
of Infusion Cuffs and Blood Pressure Cuffs
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Page 2 of 2

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