



America

CERTIFICATE

No. QS6 047218 0022 Rev. 02

Certificate Holder: **CODAN US Corporation**
3501 West Sunflower Avenue
Santa Ana CA 92704
USA

Certification Mark:



Scope of Certificate: **Manufacture and Distribution of Sterile, Single-Use IV Sets for Infusion and Transfusion Therapy, Enteral Feeding and Nasal Aspiration**

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_047218_0022_Rev.02

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

REPs Facility ID: **F002842**
Report No.: **72187171**
Effective Date: **2023-04-14**
Expiry Date: **2026-04-13**

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Date of Issue: 2023-04-18

(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 1 (excluding Part 1.6) – Full 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

Facility(ies):

CODAN US Corporation

3501 West Sunflower Avenue, Santa Ana CA 92704, USA

CODAN US MEXICO

Ave. Paseo Reforma #8950 G-1, 22116 Tijuana Baja California, MEXICO

CODAN US San Diego

Suite 130 2001 Sanyo Avenue, San Diego CA 92154, USA

Facility Scopes:

CODAN US Corporation

3501 West Sunflower Avenue, Santa Ana CA 92704, USA

Manufacture and Sales of Sterile, Single-Use IV Sets for Infusion and Transfusion Therapy, Enteral Feeding and Nasal Aspiration
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CODAN US MEXICO

Ave. Paseo Reforma #8950 G-1, 22116 Tijuana Baja California, MEXICO

Manufacture of Sterile, Single-Use IV Sets for Infusion and Transfusion Therapy, Enteral Feeding and Nasal Aspiration
REPs Facility ID: F006206

CODAN US San Diego

Suite 130 2001 Sanyo Avenue, San Diego CA 92154, USA

Distribution of Sterile, Single-Use IV Sets for Infusion and Transfusion Therapy, Enteral Feeding and Nasal Aspiration
REPs Facility ID: F006206

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