ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 118851 0001 Rev. 00

Certificate Holder: **S&S GLOVE CORPORATION**
Lot 4, D6 Street
Dat Do I Industrial Park
Phuoc Long Tho Commune
Dat Do District
78000 Ba Ria - Vung Tau Province
VIETNAM

Certification Mark:

Scope of Certificate: **Manufacture and Distribution of Non-Sterile Examination Gloves**

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

Regulatory Authority(ies): **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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 118851 0001 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006525**
Report No.: **VIN_118851_CA_2023**
Effective Date: **2023-06-21**
Expiry Date: **2026-06-20**

Date of Issue: 2023-06-26

(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

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

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

Facility(ies): **S&S GLOVE CORPORATION**
Lot 4, D6 Street, Dat Do I Industrial Park, Phuoc Long Tho Commune, Dat Do District, 78000 Ba Ria - Vung Tau Province, VIETNAM

Facility Scopes: Manufacture and Distribution of Non-Sterile Examination Gloves
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