

Manusi Nitril Serix Diamond Grip 8.5gr

+Serix

Prodicator: S&S Glove Corporation

EC-REP: CMC Medical Devices & Drugs SL



Manusi de Nitril, Textura Diamond Grip, 8.5 gr, Nepudrate, Portocalii, Serix

Caracteristici si avantaje:

- Mănuși de protecție superioară, 100% nitril, grosime triplă
- Nesterile, de unică folosință, ambidextre, cu margine rulată
- Textura Diamantată tip "Diamond Grip" pe palme si degete pentru o prindere și manevrabilitate usoară, chiar și în lucru cu uleiuri și produse chimice
- Flexibile, confortabile și ultra rezistente
- Protejează împotriva bacteriilor și fungilor
- Acest produs nu contine latex de cauciuc natural.
- Culoare: Portocaliu

Date tehnice:

- Marimi: M, L, XL
- Lungime: min 240 mm.
- Grosimea: 0.26 (±0.03) mm deget
- 0.22 (±0.03) mm palma
- 0.12 (±0.03) mm incheietura
- Greutate: 8.5g (Standard pt Marimea M)
- Alungire la rupere: min 500%(inainte de imbatranire)
- Rezistenta la rupere: min 6 N (inainte si dupa imbatranire)

Depozitare: A se pastra in ambalajul original, intr-un loc uscat si intunecat, ferit de ozon.

Testate si certificate pentru utilizare in:

- Industria Auto
- Construcții și amenajări interioare
- Grădinărit
- Industrie Ușoară
- Curățenie Profesională
- Productia si procesarea alimentelor
- Industria cosmetica

Sfat de utilizare:

- După folosire, purtatorii trebuie sa verifice vizual manusile si sa indeparteze orice contaminare de pe suprafata exterioara inainte de a scoate manusile.
- Indepartati cu grija manusile de pe maini, astfel incat manusile exterioare contaminate sa nu va atinga pielea.

Certificari si standarde:

- Medically Tested: MDR 2017/745
- PPE Regulation: PPE (EU) 2016/425
- ISO13485, ISO9001
- EN374
- CE2777, EU Type-Examination



S&S GLOVE CORPORATION

EC DECLARATION OF CONFORMITY

Manufacturers Name and Address: Lot 4, D6 Street, Dat Do I Industrial Park,
Phuoc Long Tho Commune, Dat Do District,
Ba Ria – Vung Tau Province,, Vietnam

SRN (Single Registration Number): VN-MF-000031848

Authorized Representative Name and Address (if applicable): CMC Medical Devices & Drugs S.L.
C/Horacio Lengo, 18.
CP29006 – Malaga - Spain
Phone: +34.951214054
Email: info@cmcmedicaldevices.com

We, S&S Glove Corporation, hereby declare under our sole responsibility that the product listed below complies with the provisions of the European Medical Device Regulation-MDR 2017/745.

The devices are Class I following Rule I of Annex VIII of the European Medical Device Regulation-MDR 2017/745.

We hereby also declare under our sole that the product below complies with the provisions of PPE Regulation (EU) 2016/425.

Product Identification				
Product Name	Model / Catalogue No	EMDN Code	Basic UDI-DI #	Intended Purpose
Powder Free Nitrile Examination Glove	SSG-N	T01020204	89385409170NCLFT0424229F	Nitrile Examination Glove is intended to be worn by healthcare practitioner to protect patient and user from cross contamination

The present declaration is in conformity with European Medical Device Regulation-MDR 2017/745 and PPE Regulation (EU) 2016/425.

This declaration is supported by the Quality System Approval to ISO 13485: 2016 and ISO 9001: 2015 issued by SGS United Kingdom Ltd.

Place and Date (dd/mm/yyyy) of Issue :
Ba Ria – Vung Tau, Vietnam (16/09/2023)

Company Representative Signature:

Poppy Farrah Rossa
(QA/RA Manager)



SATRA
TECHNOLOGY

Issued to:

S&S Glove Corporation
Lot 4, D6 Street
Dat Do I Industrial Park
Phuoc Long Tho Commune
Dat Do District, Ba Ria -
Vung Tau Province
Vietnam

Notified Body: 2777

SATRA customer number: P23051

EU Type-Examination Certificate

Certificate number: 2777/25409-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference: SSG-DG
Description: Powder-Free Nitrile Diamond textured examination Glove.

Available Colours: Blue, Orange, Green, Black

Sizes: S, M, L, XL, XXL

Classification:
EN ISO 374-1:2016+A1:2018 / Type B

Level	EN ISO 374-4:2019 Degradation %
6	-12.0
2	-27.7
5	15.8

EN ISO 374-5:2016
Protection against bacteria and fungi
Protection against viruses

Pass
Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0351389 2324 1, CHM0351389 2324 2, CHM0351389 2324 3, CHM0351389 2324 4, CHM0351389 2324 5

Signed on behalf of SATRA: Geoff Graham

Date first issued: 23/02/2024
Date of issue: 23/02/2024
Expiry date: 23/02/2029

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SATRA Technology Europe Limited, Bradstone Business Park, Clonoe, D15YNP, Republic of Ireland.



America

CERTIFICATE

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?qcert=QS6_118851_0001_Rev_00
TUV SUD 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

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Date of Issue: 2023-06-26

(Renee Walker)
Director, US Certification Body, MHS

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TUV®



America

CERTIFICATE

No. QS6 118851 0001 Rev. 00

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
REPs Facility ID: F006525

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(Renee Walker)
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