

Certificate Of Conformance

This is to certify that the Quality Management System of:

Medical Elastomer Development, Inc

1700 Highland Road
Twinsburg OH
44087
United States

has been assessed by ABS Quality Evaluations, Inc. and found to be in conformance with the requirements set forth by:

ISO 13485:2016

The Quality Management System is applicable to:

Manufacture of extruded silicone components for the medical device industry.

Certificate No: **47202**
Certification Date: **19 DEC 2021**
Effective Date: **04 DEC 2024**
Expiration Date: **19 DEC 2027**
Revision Date: **04 DEC 2024**



Dominic Townsend, President



ISO 13485:2016
Certificate Of Conformance
ANNEX

Certificate No.: 47202

Medical Elastomer Development, Inc

At the below facilities

FACILITY NAME	FACILITY ACTIVITY	ADDRESS
Medical Elastomer Development, Inc	Management of QMS, Manufacture of extruded silicone components for the medical device industry.	1700 Highland Road Twinsburg OH 44087 United States
Medical Elastomer Development, Inc	Material handling	1670 Enterprise Parkway Suite E, F, G Twinsburg OH 44087 United States



Certificate Of Conformance

This is to certify that the Quality Management System of:

Sanisure, Inc.

1020 Flynn Rd.
Camarillo CA
93012
United States

has been assessed by ABS Quality Evaluations, Inc. and found to be in conformance with the requirements set forth by:

ISO 9001:2015

The Quality Management System is applicable to:

Design, Manufacturing, Fabrication and Distribution of Tubing; Bottle Assemblies; and Sterile and Non Sterile Ultra-Pure Components of Glass, Polymers, Metals and Rubber; and Molding of plastic components including tooling production

Certificate No: **47986**
Certification Date: **26 DEC 2018**
Effective Date: **19 DEC 2024**
Expiration Date: **19 DEC 2027**
Revision Date: **19 DEC 2024**



Dominic Townsend, President



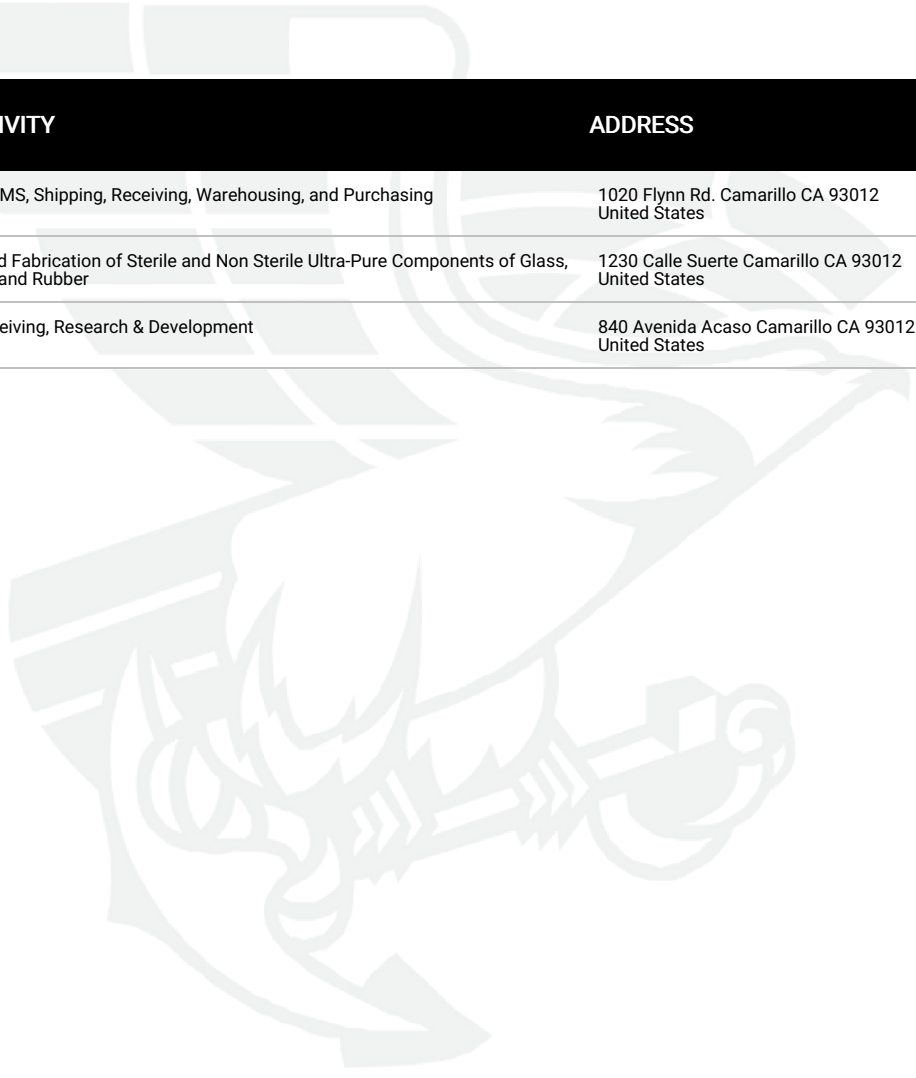
ISO 9001:2015
Certificate Of Conformance
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Certificate No.: 47986

Sanisure, Inc.

At the below facilities

FACILITY NAME	FACILITY ACTIVITY	ADDRESS
Sanisure, Inc.	Management of QMS, Shipping, Receiving, Warehousing, and Purchasing	1020 Flynn Rd. Camarillo CA 93012 United States
Sanisure, Inc.	Manufacturing and Fabrication of Sterile and Non Sterile Ultra-Pure Components of Glass, Polymers, Metals and Rubber	1230 Calle Suerte Camarillo CA 93012 United States
Sanisure, Inc.	Warehousing, Receiving, Research & Development	840 Avenida Acaso Camarillo CA 93012 United States



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 101803**

Certificate Holder: **SANISURE S.A.**
16 rue Héierchen - ZAE R. Steichen
L-4940 BASCHARAGE
Luxembourg

Scope: Supply and manufacturing of products to the biopharmaceutical industry and the life science research sector

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-12-21 until 2025-12-20.
First certification 2010

2022-12-14



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate US20/819943795

The management system of

SaniSure, Inc.

18 White Lake Road, Sparta, NJ, 07871, United States Of America

has been assessed and certified as meeting the requirements of
ISO 9001:2015

For the following activities

Designs, manufactures and distributes single-use components and systems to transfer and/or store fluid or other media.

This certificate is valid from 17 February 2023 until 17 February 2026 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 17 February 2020

Dan Seal

Authorised by
Daniel Seal

SGS North America Inc.
201 Route 17 North Rutherford, NJ 07070
t +1 (201) 508-3000 - www.sgsgroup.us.com



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

SaniSure Limited
49 Pasture Road
Stapleford
Nottingham
NG9 8HR
United Kingdom

Holds Certificate Number:

FM 01482

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture and supply of silicone rubber moulded or extruded products, the assemblies of the medical and pharmaceutical industries. These are manufactured to individual customer specifications and include profiles, tubing, cord and sheet (either solid or sponge).

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1988-02-01

Latest Revision Date: 2023-09-01

Effective Date: 2023-09-03

Expiry Date: 2026-09-02

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...making excellence a habit.™

Certificate No: FM 01482

Location	Registered Activities
SaniSure Limited 49 Pasture Road Stapleford Nottingham NG9 8HR United Kingdom	The manufacture and supply of silicone rubber moulded or extruded products, the assemblies of the medical and pharmaceutical industries. These are manufactured to individual customer specifications.
SaniSure Limited Unit 2 Quarry Hill Industrial Estate Ilkeston DE7 4RF United Kingdom	The manufacture and supply of silicone rubber moulded or extruded products. These are manufactured to individual customer specifications and include profiles, tubing, cord and sheet (either solid or sponge).
SaniSure Limited Unit D2 Fields Farm Road Long Eaton Nottingham NG10 3FZ United Kingdom	The storage of Pharmaceutical assembly components and raw material polymers and finished goods.

Original Registration Date: 1988-02-01

Latest Revision Date: 2023-09-01

Effective Date: 2023-09-03

Expiry Date: 2026-09-02

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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