

ABS Quality Evaluations

Certificate Of Conformance

This is to certify that the Quality Management System of:

Sanisure, Inc.

**1020 Flynn Rd.
Camarillo, CA 93012
U.S.A.**

(WITH ADDITIONAL FACILITIES LISTED ON ATTACHED ANNEX)

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

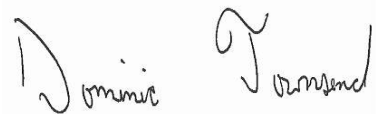
ISO 9001:2015

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

This certificate may be found on the ABS QE Website (www.abs-qe.com). For certificates issued in the People's Republic of China information may also be verified on the CNCA website (www.cnca.gov.cn).

Certificate No: 47986
Certification Date: 26 December 2018
Effective Date: 07 February 2023
Expiration Date: 19 December 2024
Revision Date: 07 February 2023



Dominic Townsend, President



Validity of this certificate is based on the successful completion of the periodic surveillance audits of the management system defined by the above scope and is contingent upon prompt, written notification to ABS Quality Evaluations, Inc. of significant changes to the management system or components thereof.

ABS Quality Evaluations, Inc. 1701 City Plaza Drive, Spring, TX 77389, U.S.A.
Validity of this certificate may be confirmed at www.abs-qe.com/cert_validation.

ABS Quality Evaluations

ISO 9001:2015
Certificate Of Conformance
ANNEX

Certificate No: 47986

Sanisure, Inc.
At Below Facilities:

Facility: 1020 Flynn Road
Camarillo, CA 93012
U.S.A.

Facility: 1230 Calle Suerte
Camarillo, CA 93012
U.S.A.

Activity: Management of QMS, Shipping, Receiving, Warehousing, and Purchasing

Activity: Manufacturing and Fabrication of Sterile and Non Sterile Ultra-Pure Components of Glass, Polymers, Metals and Rubber

Facility: Avenida Acaso
840 Avenida Acaso
Camarillo, CA 93012
U.S.A.

Activity: Warehousing, Receiving, Research & Development



Validity of this certificate may be confirmed at www.abs-qe.com/cert_validation.

ABS Quality Evaluations

Certificate Of Conformance

This is to certify that the Quality Management System of:

Medical Elastomer Development, Inc

**1700 Highland Road
Twinsburg, OH 44087
U.S.A.**

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

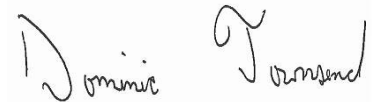
ISO 13485:2016

The Quality Management System is applicable to:

MANUFACTURE OF EXTRUDED SILICONE COMPONENTS FOR THE MEDICAL DEVICE INDUSTRY.

This certificate may be found on the ABS QE Website (www.abs-qe.com). For certificates issued in the People's Republic of China information may also be verified on the CNCA website (www.cnca.gov.cn).

| | |
|-------------------------|------------------|
| Certificate No: | 47202 |
| Last Expiry Date: | 19 December 2021 |
| Original Approval Date: | 20 December 2012 |
| Certification Date: | 02 February 2022 |
| Effective Date: | 09 February 2023 |
| Expiration Date: | 19 December 2024 |
| Revision Date: | 09 February 2023 |



Dominic Townsend, President



Validity of this certificate is based on the successful completion of the periodic surveillance audits of the management system defined by the above scope and is contingent upon prompt, written notification to ABS Quality Evaluations, Inc. of significant changes to the management system or components thereof.

ABS Quality Evaluations, Inc. 1701 City Plaza Drive, Spring, TX 77389, U.S.A.
Validity of this certificate may be confirmed at www.abs-qe.com/cert_validation.

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

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