Regulatory Information Overview & Instructions For Appropriate Use

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade

Regulatory Information Overview

Country of Origin

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade - are manufactured in France.

Manufacturing Location(s)

SAINT-GOBAIN PERFORMANCE PLASTICS FRANCE

Z.I. de Chesnes, 5 Rue du Dauphiné,

F-38297 Saint Quentin-Fallavier Cedex, France

Phone : +33 (0)4 74 94 82 22 / Fax : +33 (0)4 74 94 23 41

http://www.medical.saint-gobain.com

Site Certifications

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade - are manufactured in Saint-Quentin-Fallavier according to ISO 9001 and ISO 13485 standards.

The manufacturing of **SILMEDIC® CP 61 & VERSILIC® S60V34B. - Medical Grade** - articles is carried out in controlled environment for the finishing and packaging room, i.e ISO 7 class. A strict follow up of the environment can guaranty the cleanliness and a low controlled bio burden.

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Product description

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade - are a silicone rubber designed for extruded tubing, developed for medical applications.

	SILMEDIC® CP 61 & VERSILIC® S60V34B. Medical Grade
Material	Silicone rubber
Color	Translucent
Specific gravity (NF ISO 2781)	1.14
Shore A hardness (NF ISO 7619-1)	60 ShA
Tensile strength (NF ISO 37)	10.0 MPa
Elongation at break (NF ISO 37)	320 %
Tear strength (NF ISO 34-1 Ba)	20.0 N/mm

These properties have been measured on ASTM molded slabs.

These values are typical values and are not intended for use in preparing specifications.

Chemical characterization

Each batch of raw material used for the manufacturing of **SILMEDIC® CP 61 & VERSILIC® S60V34B. - Medical Grade** - product is tested and complies to European Pharmacopoeia (§3.1.9 “Silicone elastomer for closures and tubing”).

These tests are carried out on extruded tubing whose wall thickness and internal diameter are determined by our internal specifications.

Tests	**Limit values of European Pharmacopeia**
Phenylated compounds	< 0.4
Mineral oils	Fluorescence
Residual peroxides	< 0.08 %
Acidity	< 2.5 ml NaOH 0,01 N
Alkalinity	< 1 ml HCl 0.01 N
Soluble substances in hexane	< 3.0 %
Reducing substances	< 1 ml
Volatile matter	< 0.5 % (peroxide)

Sterilization

Items are supplied non sterile by SGPP France.

The items which are intended to be sterilized benefit from a low and stable bioburden. Thus, any further sterilization method can be used after user's validation.

Sterilization methods are:

- Ionization: Beta or Gamma
- Steam (134°C)
- Heat
- Ethylene Oxide

Materials of Construction

The material is a silicone rubber crosslinked with peroxide.

Shelf Life and Storage

The products should be stored in their packaging, in the absence of mechanical stress, at a maximum temperature of 45 ° C (113°F), in a dry place and away from light.

Respecting these storage conditions, the products have a shelf-life determined before use. The expiry date is indicated on the label in this format:

JJ/MM/YY

Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on information provided by our suppliers, bovine or other animal derived content materials are not used in the raw materials used to manufacture the **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade** - as defined in specification EMA/410/01 rev.3.

Saint-Gobain does not use, or add, any substances or materials with animal content in the manufacturing process that come in contact with silicone rubber designed for extruded tubing, developed for medical applications.

Bisphenol A (BPA)

BPA is not used in the formulation or manufacture of Saint-Gobain for silicone rubber designed for extruded tubing, developed for medical applications.

Biocompatibility

Raw materials used to produce **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade** - have been tested by the raw material suppliers according to both the USP Class VI standards and the ISO 10993. Moreover the biocompatibility of the **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade** – has been tested on tubing according to the ISO 10993 and products meet the following requirements:

			Raw materials (Suppliers)	**SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade**
USP	Class VI	Acute Systemic Toxicity	o	Not tested
		Intracutaneous Toxicity	o	Not tested
		7 day Implantation study	o	Not tested
ISO	10993-3	Genotoxicity	x	o
	10993-4	Hemolysis	o	o
	10993-5	Cytotoxicity	x	o
	10993-6	Implantation	x	Not tested
	10993-10	Acute Intracutaneous reactivity, delayed contact sensitization	x	o
	10993-11	Systemic toxicity	x	o
		Pyrogenicity	o	Not tested

o : tested & compliant x : suppliers do not claim any compliance

Latex

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade - is not made using latex and do not come in contact with latex materials during the manufacturing or packaging process.

Phthalates

Phthalates are not used in the formulation or manufacture of Saint-Gobain **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade**. These include: di(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), di-isobutyl phthalate (DIBP), di-iso-decyl phthalate (DIDP), di-iso-nonyl phthalate (DINP), di-n-octyl phthalate (DNOP) and di-n-pentyl phthalate (DNPP). They may be present in a concentration limit of 0.1%.

Food contact status

SILMEDIC® CP 61 & VERSILIC® S60V34B. products meet FDA Regulations CFR 177.2600 (e)

REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)

The European Union REACH regulation of December 18, 2006 requires companies which manufacture or import chemical substances into the European Union in quantities of one metric ton or more per year to register these substances with the European Chemicals Agency (ECHA). Saint-Gobain Performance Plastics complies with the provisions of REACH where applicable.

SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade - does not contain materials described as **S**ubstances of **V**ery **H**igh **C**oncern (SVHC) as defined by the European Union/ECHA.

Restriction of Hazardous Substances (RoHS) & Coalition of Northeastern Governors (CONEG)

Per RoHS Directive 2011/65/EU, **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade -** is RoHS-compliant and therefore adhere to the guidelines below:

- Concentration of Lead (Pb), Mercury (Hg), Hexavalent Chromium (CrVI), PBB (Polybrominated Biphenyls) or PBDE (Polybrominated Diphenyl Ethers) in product: Not to exceed 1,000 ppm.

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- Concentration of Cadmium in product: Not to exceed 100 ppm individually or for the total incidental content per CONEG requirement limits.

None of the currently listed RoHS exemptions are used in the manufacturer of this product.

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Warnings

SILMEDIC® & VERSILIC® products are not intended to be in contact with blood, other body fluids or tissues for a period longer than 29 days.

Traceability

Each batch carries a lot number. This number secures the traceability from the identification of the raw material up to the final user.
This lot number is required for the processing of any claim.

Responsibility

This Overview document is intended to provide users of Saint-Gobain **SILMEDIC® CP 61 & VERSILIC® S60V34B. – Medical Grade** with the information necessary to assess the suitability of these products for use in their intended application.

Saint-Gobain has no run any analysis for concentration levels for the regulatory compliances listed above. It is the responsibility of the customers to determine whether their use of Saint-Gobain product is safe, lawful and technically suitable for their intended purpose.

Our responsibility is limited to the characteristics stated in this document.

In addition, we reserve the right to bring about modifications to our compounds or manufacturing procedures providing that these amending do not affect the characteristics mentioned in this document.