

# LAKE PRODUCTS LTD

MANUFACTURERS AND DISTRIBUTORS

9 July 2024

## Declaration of Compliance on Food Contact Materials other than Plastics

This statement concerns materials and articles of other materials than plastic intended for food contact.

The declaration reflects the requirement of Regulation EC 1935/2004.

The covered materials and articles are intended for use in the dairy industry.

Independent Test Certification confirming compliance as stipulated in Regulation EC 1935/2004 on materials intended for contact with food.	See attached Certificate of Compliance Newman Sanitary Gasket Company Report dated 18 September 2023 and Lake Products Limited Letter of Conformity dated 2 July 2024.
Description of the object/group of objects	Pre-Sure™ Cap Diaphragm
Description of material	Silicone
Specification on the use of the material or article	Temperature range: 5°C to +90°C Hygienic Red Silicone (Class VI) Rubber selection according to rubber material specification For use in food, dairy & pharmaceutical manufacturing production
Ceramics & Glass	N/A
Regulation EC 1935/2004	Lake Products Limited confirms that the materials used meet the relevant provisions set out in the Regulation
Regulation EC 2023/2006	Lake Products Limited conforms with the Regulations set down for good manufacturing practice for the production of items intended to come into contact with food
Supporting Materials	Lake Products Limited will provide supporting documentation on request

# NEWMAN Sanitary Gasket Company

964 W. MAIN STREET • PO BOX 222 • LEBANON, OH 45036 • PHONE 513-932-7379 • FAX 513-932-4493

## CERTIFICATE OF COMPLIANCE

Newman Sanitary Gasket Company certifies that the pharmaceutical grade elastomer compounds, EPDM (2107, 2127), Silicone (4137, 4147, 4227, 4247), Viton (3107, 3107ETP, 3197GF, 3207, 3227) and Silverback (50% PTFE/50% 316 Stainless Steel, 9110) from which we manufacture our parts under prescribed manufacturing procedures for pharmaceutical products have been tested and certified by the Toxicon Laboratory in Woburn, MA, to be in compliance with USP <87> Biological Reactivity Tests, in Vitro and USP <88> Class VI Biological Reactivity Tests, in Vivo, (121°C, all compounds except 3107ETP, 3227 and 4147 (70°C).

Dow Corporation has certified that their medical grade silicone compound Q7-4780 (Newman compound 4749) is in compliance with USP <87> Biological Reactivity Tests, *in Vitro* and USP <88> Class VI Biological Reactivity Tests, in Vivo, (121°C).

Newman Sanitary Gasket Company certifies that our Teflon® parts are made from virgin Teflon® which has been tested by DuPont to be in compliance with USP <87> Biological Reactivity Tests, in Vitro and USP <88> Class VI Biological Reactivity Tests, in Vivo, (121°C).

Newman Sanitary Gasket Company certifies that the following compounds used to manufacture our sanitary process piping gaskets, "O"-rings and custom molded parts are in compliance with the 3-A Sanitary Standards, Procedure 18-03. These compounds are Buna (1107), EPDM (2107), Silicone (4137), Viton (3107, 3127, 3207, 3227).

Newman Sanitary Gasket Company certifies that the Teflon® compound used to manufacture our sanitary process piping gaskets is in compliance with the 3-A Sanitary Standards, Procedure 20-27.

Newman Sanitary Gasket Company also certifies that all compounds mentioned within this document comply with the FDA Code of Federal Regulations for rubber and rubber-like materials under Title 21, paragraph 177.2600 for repeated use in contact with food. The Teflon® resins from which our parts are produced are in compliance with the FDA Code of Federal Regulations under Title 21, Paragraph 177.1550.

Newman Sanitary Gasket Company also certifies that the gaskets manufactured by Newman are in compliance to relevant sections of ASME BPE (current version).

Newman Sanitary Gasket Company also certifies that the compounds used to manufacture our gaskets do not contain animal derivative ingredients (ADI).

Customer Name: LAKE PRODUCTS LTD  
P.O. Number: 00020359  
Item: SPE-014219-01RX 64MM OD USPCLVI RED SILICONE V31.2 DIAPHRAGM  
NSGCO Part Number: SPE-014219-01RX  
Customer Part Number:  
Quantity: 950  
Batch Number: 141299  
Compound: 4137  
Cure Date: 3Q23  
Date Signed: September 18, 2023



Betsy J. Newman, Vice President

# LAKE PRODUCTS LTD

MANUFACTURERS AND DISTRIBUTORS

2 July 2024

To Whom it may Concern

We hereby confirm that the materials used for the manufacture of Pre-Sure™ Cap products have the following properties:

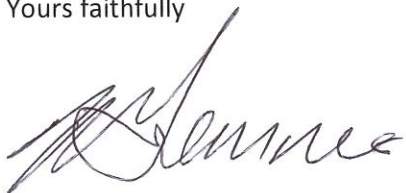
Material	Class VI	Thickness
Silicone	Compound: 4137	2mm

Material	Grade	Thickness
Stainless Steel	316L	5mm

Material	Temperature Range	Thickness
Silicone / Stainless	5° to +90°C	2mm

Material	Unit	Thickness	Thermal Conductivity
Silicone	W/mK	2mm	0.25

Yours faithfully



**Mike Sumner**  
General Manager