

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