



Certificate of Compliance

Cole-Parmer Product Number: **96410-13**

Issued Date: **15 July 2022**

Lot#/Batch#: **H033M11004**

Your PO#: **0**

CP Order #: **0**

Description **TUBING MFLEX SILICONE #13 25'**

Compound: **Tubing:QCF7-5201 Proprietary BioMed Grd. Elastomer**

Specification: **Platinum Cured Silicone Rubber**

Cole-Parmer certifies that, according to the manufacturer, the product described meets the specifications set forth in this certificate, subject to the disclaimers set forth herein.

All raw materials used in these tubing products meet the requirements of the FDA 21, subchapter B, CFR 177.2600, Rubber Articles Intended for Repeated Use in Contact with Food (Food-Grade).

Meets most criteria for selected tests of Dairy 3-A Sanitary Standards

These products have been manufactured in accordance with the principles of Good Manufacturing Practices in an ISO 14001:2004 Environmental Management System and ISO 9001 registered facility.

The site is registered with the Department of Health and Human Services, Public Health Service and Food and Drug Administration (FDA) and is inspected.

Tubing is rigorously tested, fully traceable, comprehensively documented and thoroughly managed for contamination.

The elastomer meets or exceeds the requirements of all USP Class V Extractables tests and exceeds the requirements for the USP Class VI Plastics Test.

The elastomer has also been tested and meets the requirements for USP pyrogens, tissue culture tests. All tests passed according to protocol.

The elastomer meets ICH Q3D permitted concentrations (ppm) for parenteral applications

Meets European Pharmacopoeia 9th edition 3.1.9 * this only applies to the tubing and not the labeling ink.

* Please Note & where applicable - This item is provided in bulk and individual packages will be labeled 96410-xx. (where as xx represents the size). The compound and specifications are the same.

Not to be used for any hospital or patient care use, such as for temporary insertion. Not to be used in human implantation, or human contraceptive, reproductive, obstetric or gynecological applications.

It is the responsibility of the user to conduct tests that are deemed necessary to determine the suitability of this product for any particular use.

Cole-Parmer certifies that, according to the most recent information provided by the manufacturer, the product described meets the specifications set forth in this certificate, subject to the disclaimers set forth herein.

This certification applies only to the condition of the above-described product in the unopened package. Cole-Parmer cannot and does not assume any responsibility for any failure of the product to meet this Certificate of Compliance that results from any handling or use subsequent to opening the package.

Cole-Parmer expressly warrants that the product listed above conforms only to the specifications herein, subject to the disclaimers listed above, if any. Except as otherwise set forth in writing by Cole-Parmer, there are no other warranties, express or implied, including without limitation warranties of marketability or fitness for a particular purpose, use or application, that apply to this certificate or the subject product. It is the responsibility of the user to determine the suitability of the subject product for any particular use or application.

Michael Whitaker
Regulatory Compliance Manager