



Certificate of Compliance

Cole-Parmer Product Number: **06424-17**

Issued Date: **01 July 2022**

Lot#/Batch#: **27916232**

Your PO#: **0**

CP Order #: **0**

Description **TUBING MFLEX C-FLEX #17 25'**

Compound: **R70-001-000**

Specification: **C-FLEX®**

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.

Product is manufactured in accordance with quality regulation CFR Title 21, Part 820 Quality System Requirements (GMP)

Thermoplastic Elastomer used to produce C-Flex® products meets standard physical property requirements as tested on ASTM slabs.

Thermoplastic Elastomer used to produce C-Flex® products satisfies the requirements of the following tests:

European Pharmacopeia 6.0, 2008: Chapter 3.2.9 Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze-dried Powders.

Hemolysis Study - ISO 10993-4, 2002, Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, Hemolysis - Rabbit Blood, Indirect Contact

Physicochemical Total Extractables - USP 32, NF 27, 2009; <381> Elastomeric Closures for Injections.

Rabbit Pyrogen Test (Material Mediated) -ISO

ISO 10993-11, 2006, Biological Evaluation of Medical Devices- Part 1: Tests for Systemic Toxicity.

USP 32, National Formulary 27, 2009. <151> Pyrogen Test.

Physicochemical - USP 32, National Formulary 27 (USP) General Chapter <661>, Container-Plastics (2009) (i.e Heavy Metals)

Thermoplastic Elastomer used to produce C-Flex® products are Animal Derived Component Free (ADCF)

USP Class VI Post-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo. ISO 10933-5, Tests for Vitro Cytotoxicity

USP Class VI Pre-Gamma, USP 32 NF 27, 2009, <88> Biological Reactivity Tests, In Vivo.

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