

Certificate of Compliance

Description:	20 Liter Rocker Bag	Catalog #:	91-200-78
		Lot #:	99E0C-0000
		Expiration Date:	MAY/2025
Storage	10 to 34°C	Irradiation Date:	MAY/2022
		Country of Manufacture	USA

Notes:

This is to certify that this product has been manufactured in a manner compliant with current Good Manufacturing Practices (cGMPs), FDA regulation 21 CFR part 820 and ISO 13485 Quality Standard. This product has been inspected and tested in accordance with currently approved Mediatech, Inc. applicable material specification and drawing requirements.

The fluid pathways are classified USP VI and/or ISO-10993. The fluid path raw materials conform to the European guidance EMA/410/01 and the U.S. CFR Title 9 of Part 94.18

For research use and further manufacturing use only; Not for use in diagnostic or therapeutic procedures. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

Test	Specification	Units	Results
Irradiation Dose	25.0 – 45.0	kGy	Pass

Inspection: This Lot of Container System has been 100% visually inspected per specification.

Biological Reactivity: All product contact materials have passed USP Class VI testing (USP<88>) and/or ISO10993.

Physiochemical: All product contact films have passed USP Physiochemical Tests for Plastics (USP<661>).

For further information, contact Corning Scientific Support at 800-492-1110 or ScientificSupport@corning.com

Following signatures indicate the above material has met all quality specifications and has been reviewed by a Quality representative.

Written By/Date: Elisabeth Walter 06JUN2022

Reviewed By/Date: _____

09 JUN 2022



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