

CERTIFICATE OF ANALYSIS

BioProfile Control Level 9 Lot Number 23350001 Catalog Number 43473 Exp Date 2025-03

 $\begin{array}{cc} \text{Spec} & \text{Pass/Fail} \\ \text{Particles/mL} & 55.00 \times 10^5 - 65.00 \times 10^5 & \text{Pass} \end{array}$

This product is certified to have been manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Amishi.M

Approval

QC Inspector Title

<u>1/19/2024</u> Date