

CERTIFICATE OF ANALYSIS

BioProfile Control Level 8 Lot Number 23293019 Ref Number 43472 Exp Date 2025-01

Spec

Pass/Fail

Particles/mL

 $5.50 \times 10^{5} - 6.50 \times 10^{5}$

Pass

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

Approval

QC Inspector

Title

11/29/2023

Date