

CERTIFICATE OF CONFORMANCE

BioProfile® FLEX2™ ESM Shut-Down Cartridges Lot Number 24316086

Part Number 60612 Exp Date 2026-09-27 Date of Manufacture 2024-09-27

Shutdown Solution Lot Number: 24271075 Contents Spec Result N/A

Aqueous Solution with Preservative Present

This product is certified to have been manufactured 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).

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

Approval

QC Inspector Title

11/15/2024 Date