

CERTIFICATE OF CONFORMANCE

BioProfile® FLEX2™ ESM Shut-Down Cartridges Lot Number 23087083

Part Number 60612 Exp Date 2025-03-02 Date of Manufacture 2023-03-02

Shutdown Solution Lot Number: 23061041

Contents Spec Result **Aqueous Solution** N/A Present

with Preservative

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

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Approval

QC Inspector Title

03/31/2023 Date