

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] ESM Shut-Down Cartridges Lot Number 23305025

Part Number 60612 Exp Date 2025-10-30 Date of Manufacture 2023-10-30

Shutdown Solution Lot Number: 23303047 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

Haneen Aldarwish

Approval

QC Inspector Title

11/03/2023 Date