

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] ESM Shut-Down Cartridges Lot Number 25128020

Part Number 60612 Exp Date 2027-03-31 Date of Manufacture 2025-03-31

Shutdown Solution Lot Number: 25090014

<u>Contents</u> <u>Spec</u> <u>Result</u>

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

Amishi.M

Approval

QC Inspector Title

05/14/2025 Date