

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] ESM Shut-Down Cartridges Lot Number 23010025

Part Number 60612 Exp Date 2024-12-20 Date of Manufacture 2022-12-20

Shutdown Solution Lot Number: 22354049

<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

Approval

QC Inspector

Title

01/12/2023

Date