

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] ESM Shut-Down Cartridges Lot Number 22243088

Part Number 60612 Exp Date 2024-07-11 Date of Manufacture 2022-07-11

Shutdown Solution Lot Number: 22192030 <u>Contents</u> <u>Spec</u> <u>Result</u>

Present

Aqueous Solution N/A 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

09/06/2022 Date