

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] ESM Shut-Down Cartridges Lot Number 23058031

Part Number 60612 Exp Date 2025-01-17 Date of Manufacture 2023-01-17

Shutdown Solution Lot Number: 23017087

 $\begin{array}{ccc} \underline{\text{Contents}} & \underline{\text{Spec}} & \underline{\text{Result}} \\ \text{Aqueous Solution} & \text{N/A} & \underline{\text{Present}} \end{array}$

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

03/01/2023 Date