

CERTIFICATE OF CONFORMANCE

BioProfile[®] FLEX2[™] CDV Shut-Down Cartridge Lot Number 23229036

Part Number 60611 Exp Date 2025-07-19 Date of Manufacture 2023-07-19

Shutdown Solution Lot Number: 23200023

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

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

Amishi.M

Approval

QC Inspector Title

08/21/2023 Date