

Certificate US23/00000323



The quality management system of

# Beeken Biomedical, LLC

378 Page Street, Suite 201, Stoughton, MA, 02072 United States of America  
Facility number: F006635

has been assessed and certified as meeting the requirements of

## MDSAP (ISO 13485:2016)

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, manufacture, and distribution of sterile hemostatic dressings.

This certificate is valid from Effective date 2023-07-13 until Expiry date 2026-07-12 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 2023-07-13

Authorised by  
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