

Certificate US23/00000323

The quality management system of

Beeken Biomedical, LLC

SGS

100 Carlson Avenue, Building 25, Room 019C, Newton, MA 02459, United states of America
Facility number: F006635

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General

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 2026-07-12 until Expiry date 2029-07-12 and remains valid subject to
satisfactory surveillance audits.

Issue 4. Certified since 2023-07-13



Authorised by

Virginie Siloret

Head of Certification and Compliance

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at
www.SGS.com.



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

