



COOK BIOTECH INC.  
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## CERTIFICATE OF COMPLIANCE

22 February 2023

Cook Biotech is a member of Cook Group of Bloomington, Indiana and is an FDA registered medical device manufacturer regulated under the Quality System Regulations (QSR) 21 CFR 820. Our registration number is 1835959.

Cook Biotech is also certified by BSI as compliant to the European Union requirements per ISO 13485 and MDSAP. We are also certified by BSI to meet the United States (FDA) Canadian (HC), Brazilian (ANVISA), Australian (TGA), and Japanese (MLHW) quality system requirements. The last BSI inspection certificate was issued on 02 Feb 2022.

All Cook Biotech products made from porcine small intestinal submucosa (SIS) that are marketed in the U.S. have received FDA 510(k) clearance. All products marked in other countries have received approval from the appropriate governing bodies.

For SIS products from Cook Biotech, all animals are sourced in the United States. Farms are inspected annually by Cook Biotech and by a veterinarian. Animals are raised under conditions compliant with EN ISO 22442.

SIS products from Cook Biotech are animal-derived and acellular, therefore they are exempt from FDA Regulations (21 CFR parts 1270-1271) HUMAN CELLS, TISSUES AND CELLULAR AND TISSUE\_BASED PRODUCTS per 21 CFR 1271.3(d)(6).

On 17 November 2006 the FDA issued a document to detail tracking requirements for medical devices. Under these rules, tracking is required only when the FDA issues a Tracking Order. No Tracking Orders have ever been issued for any SIS product from Cook Biotech. In short, no tracking requirements have ever been applicable to any SIS product from Cook Biotech under any of the JCAHO, FDA, or international regulations, current or previous.

On 26 October 2010, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) issued a letter regarding SIS products from Cook Biotech and stated "[SIS products from Cook Biotech] are not subject to the Joint Commission Tissue Storage and Issuance Standards."

Curt Bogue  
Director of Quality Assurance

Mike C. Hiles  
Senior Vice President and CSO