UDI LABELING

Enforcement & Data Submission

September 24, 2013 the FDA **ESTABLISHED A UNIQUE IDENTIFICATION SYSTEM** to adequately identify medical devices

GTIN
GLOBAL TRADE ITEM NUMBER
an item barcoding system developed by the non-profit organization GS1. GS1 IS AN FDA-ACCREDITED ISSUING AGENCY

UDI
UNIQUE DEVICE IDENTIFICATION #
Identifies a product. Always numeric, non-intelligent number, unambiguous

ENFORCEMENT OF UDI LABELING and data submission for Class 1 medical devices, **INCLUDING DISPOSABLE EXAMINATION AND SURGICAL GLOVES,** has been extended to

To be compliant, the labeler must submit information of each device to FDA's Global Unique Device Identifier Database (GUDID), which serves as the repository of key device identification data. THE LABELER IS DEFINED AS THE OWNER OF THE BRAND. THE OWNER OF A PRIVATE LABEL BRAND IS THEREFORE THE LABELER. All such devices must be properly labeled with a UDI and be registered on GUDID by **SEPTEMBER 24, 2022** by the labeler

GS1 develops global standards for the IDENTIFICATION OF GOODS

GS1 The global language of business

UPC
UNIVERSAL PRODUCT CODE

12 DIGITS

14 DIGITS

ENFORCEMENT OF UDI LABELING

Enforcement of UDI labeling and data submission for Class 1 medical devices, including disposable examination and surgical gloves, has been extended to September 24, 2022. To meet this compliance date, Sempermed has labeled each of our products with a UDI, in the form of 12 and 14 digit Universal Product Codes (UPC), which were created using GTIN (barcoding) software provided by GS1, and registered on GUDID. Accurate and synchronized data improves supply chain efficiency and patient safety by reducing picking errors, facilitating faster product recalls, enabling efficient tracking of medical devices, while enhancing inventory management.