

# UDI LABELING

## Enforcement & Data Submission

September 24, 2013 the



**ESTABLISHED  
A UNIQUE  
IDENTIFICATION  
SYSTEM**  
to adequately  
identify medical devices

ENFORCEMENT OF UDI LABELING and data submission for Class 1 medical devices, **INCLUDING DISPOSABLE EXAMINATION AND SURGICAL GLOVES,** will begin on



GS1 develops global standards for the IDENTIFICATION OF GOODS



**GTIN**  
GLOBAL TRADE ITEM NUMBER

an item barcoding system developed by the non-profit organization GS1. GS1 IS AN FDA-ACCREDITED ISSUING AGENCY

**UPC**  
UNIVERSAL PRODUCT CODE

**NEW GTIN UPC**  
(inner boxes)



**12 DIGITS**

**NEW GTIN UPC**  
(outer cartons)



**14 DIGITS**

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



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, 2020** by the labeler.

### ENFORCEMENT OF UDI LABELING

Enforcement of UDI labeling and data submission for Class 1 medical devices, including disposable examination and surgical gloves, will begin on September 24, 2020. 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.