



Bracco Diagnostics Inc. GS1 / GTIN Transition Frequently Asked Questions (FAQs) & Answers

To comply with the U.S. Food and Drug Administration ruling on Unique Device Identification (UDI) and improve supply chain efficiency, Bracco Diagnostics is transitioning to a GS1 compliant barcode. The following information contains answers to frequently asked questions concerning UDI, the GS1 barcode, and Bracco Diagnostics product labeling. If you have questions or need additional information with these product changes, please contact Bracco customer service at 1-877-272-2269 (1-877-BRACCO9).

1. What are the GS1 Standards?

GS1 is the most widely used supply chain standard in the world, spanning across many different industries. They drive supply chain efficiency, traceability and accuracy.

Click [here](#) to learn more about GS1.

2. What is a Global Trade Item Number or GTIN?

A Global Trade Item Number or GTIN is a unique identifier for a product from manufacturing through distribution and use. The GTIN is typically a 14-digit numeric code which includes a company prefix followed by product identification numbers. The GTIN, as well as other key product attributes (e.g., expiration date, lot/batch number, etc.), is contained within the GS1 barcode.

Per The Global Language of Business web site, “These are the numbers behind the barcodes. Used in both the physical and digital worlds, GS1 identification numbers uniquely distinguish products, logistics units, locations, assets, documents, and relationships across the supply chain—from the manufacturer to the consumer.”

3. Why is Bracco moving to the GTINs and GS1 barcodes now?

Bracco has adopted the GTIN standard to comply with the FDA ruling on UDI and to improve supply chain efficiency and product traceability.

4. What item numbers should be used to order Bracco products?

Orders should continue to be placed using the REF/SKU number at this time.

5. Where can I get a list of GTIN's?

Click [here \(PDF\)](#) for a detailed GTIN cross-reference chart that includes a complete list of Bracco products affected by GS1 standards. Each product is identified by both a Bracco and a former E-Z-EM SKU number and a product description.

6. How do these changes impact healthcare providers?

These changes primarily impact healthcare providers which currently scan or plan to scan product labeling barcodes to order product and/or manage inventory within their supply chain. These providers will need to update their Materials Management Information System. They will need to add the new GTIN's in addition to the existing REF/SKU numbers.

For more information about a UDI system, click [here](#) to link to the U.S. FDA website.

7. Is the GTIN replacing the REF/SKU number on all products?

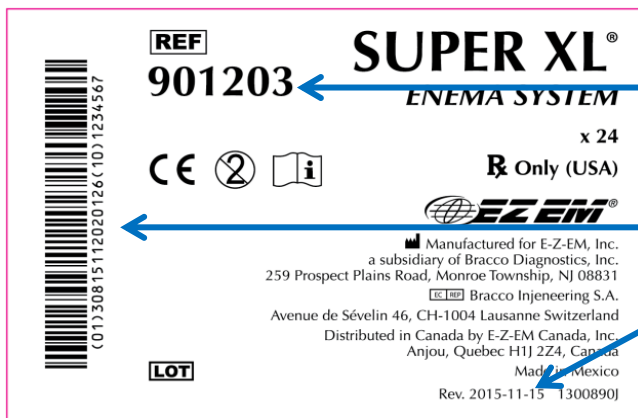
No. The REF/SKU number will remain on the label in human readable form. Customers should continue to use the REF/SKU number to re-order product.

8. What product information does the new label contain and what does a GS1 compliant label look like?

The new label can feature GS1 linear barcodes and/or 2D datamatrix symbols (when necessary). Information about the device, batch number, manufacturing date, and the expiration date, is contained in one concatenated barcode, and is collected with a single scan. If the healthcare provider does not require all of the information in the bar code, the software system or barcode scanner needs to be configured to accept only the needed portion of the information.

Below is a sample of the label revisions in which you can expect:

UDI Compliant Label Sample



- Where applicable, the legacy SKU numbers (i.e., E-Z-EM former four-digit number), have been replaced with the Bracco six-digit SKU number.
- A new UDI compliant barcode replaces the legacy barcode.
- The date format complies with new requirements (YYYY-MM-DD)

9. What is the timeline for Bracco products to transition to GTINs and GS1 barcodes?

The transition to the new UDI compliant label began in July 2016 for all applicable products that were impacted. All manufactured products will now contain the new UDI compliant labels. You may see a mix of inventory while existing product is depleted throughout the distribution channels.

10. Are other medical device manufacturers using these GS1 Standards?

Yes. Most major medical device manufacturers across the healthcare industry have or are planning to adopt and implement GS1 compliant barcodes.

11. Do I need to return current inventory that doesn't have the new GS1 compliant labeling?

No.

12. Who can I contact for more information or help with GTINs and/or GS1 barcode scanning?

For more information, please contact Bracco Customer Service at 1-877-272-2269. Click [here](#) for a detailed GTIN cross-reference chart that includes a complete list of Bracco products affected by GS1 standards.