KAISER PERMANENTE®

GS1® HEALTHCARE REQUIREMENTS
FOR VENDORS, CONTRACTORS, AND SUPPLIERS

A. Definitions.

"Customer" means a Kaiser Permanente entity purchasing goods or services from Supplier.

"*Kaiser Permanente*" means the integrated health care delivery organization doing business as Kaiser Permanente®, which includes Customer and its affiliates.

"*Product*" means a medical device or product.

"*Supplier*" means a vendor, contractor, or supplier who is providing Products to a Customer.

B. Requirements. Kaiser Permanente supports and is enforcing the implementation of the GS1 Unique Device Identification "UDI" standards in the health care industry as the preferred system for marking medical devices and products (Class 1, 2, and 3) with a unique device identifier at all packaged units (e.g., case, box) and especially for the lowest packaged unit of use (each). Kaiser Permanente also supports an accelerated timeline for the implementation of UDIs using the GS1 Standard in an effort to improve the safety and effectiveness of medical devices and products.

Kaiser Permanente requires each Supplier of Products to implement the GS1 standard for UDI, and label packages as described below:

(i) Publication of GTIN and Associated Attributes. Supplier must assign a GTIN to identify each Product at all applicable levels of packaging, including the lowest unit of patient use (e.g. case, box, each) and publish timely and accurately to the FDA GUDID. Submission of all regulated data fields, and those designated as optional but necessary for healthcare needs.

(ii) Data Availability. Supplier will actively partner with Kaiser Permanente and selected Master Data Management (MDM) to enhance data availability (e.g., publishing URL's for available digital instructional material to EUDAMED, 3D images, etc.).

(iii) Labeled Inventory. Supplier will only ship Products to Kaiser Permanente labeled in accordance with the FDA UDI Rule at all levels of packaging (e.g. case, box, each) using the GS1 labeling system requirements, including labeling each Product with a GS1-compliant barcode at the lowest unit of patient use, preferring a single barcode on package in the 2D format.

C. Audit. Supplier is responsible for maintaining readily available documentation, photographs and product packaging that will enable Kaiser Permanente to reasonably audit compliance with these requirements.

D. Failure to Comply. If Supplier fails to provide Kaiser Permanente with compliant GS1-labeled shipped Products at the lowest unit of patient use or fails to ensure accurate published data for consumption, then Supplier must reduce the price of each non-compliant Product to Kaiser Permanente by 10% until the Product labeling is compliant with these GS1 Requirements.