Carestream

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

July 23rd 2015

Dear Valued Carestream Customer,

Carestream is currently aligning our operations to GS1 standards and compliance to the FDA's Unique Device Identification (UDI) System; Final Rule. We wanted to give you advance notification of changes that you will see to our product-labeling and transactions so that you can prepare your internal operations accordingly. This is a high-level overview. Subsequent communications are planned that will provide more detail as our project progresses.

From our perspective, the GS1 system of standards provides a superior solution in addressing all aspects of product identification, product barcoding, and electronic trading transactions necessary to achieve our goals while ensuring compliance with key regulations. Carestream believes that the GS1 system of standards will continue to be the predominant standards-based solution for achieving compliance with UDI requirements between trading partners.

The use of GS1 standards is expected to:

- Drive complexity out of routine operations,
- Improve patient safety, and
- Ensure compliance with key regulations.

Carestream will also support the healthcare industry's adoption of the Global Location Number (GLN), Global Trade Identification Number (GTIN) and the Global Data Synchronization Network (GDSN). These standards are imperative to meeting the FDA's UDI requirements and supporting the data communication needs of our customers.

- **GLN (Global Location Number):** A GS1 endorsed method for identifying a company in e-commerce transactions.
- **GTIN (Global Trade Item Number):** A GS1 endorsed method for uniquely identifying a part at its various saleable units.
- **GDSN (Global Data Synchronization Network):** A GS1 endorsed global database to maintain key descriptive elements for parts assigned to GTIN numbers.

Through this process, Carestream is committed to achieving UDI compliance in advance of the timelines required by the FDA:

- **Sept. 24, 2014:** UDI Class III Devices and devices licensed under the Public Health Service Act (PHS Act)
- **Sept. 24, 2015:** UDI Class II and Class I FDASIA Implantable, Life Supporting, Life Sustaining; Life Supporting, Life Supporting Direct Marking (as required)
- **Sept. 24, 2016:** UDI Class II Devices; Class III Direct Marking (as required)
- **Sept. 24, 2018:** UDI Class I and Class U Devices; Class II Direct Marking (as required)
- **Sept. 24, 2020:** UDI Class I and Class U Direct Marking (as required)

We hope you find this information helpful in understanding these important product-labeling and transactional changes. If you have any questions or concerns, we encourage you to reach out to us through our *Contact Us* section at http://www.carestream.com/udi/.

Kind Regards,

John T. Davidson M.S.
Executive Director, Regulatory Affairs & Quality Management Systems

Resources

See below for a list of resources to assist you in understanding the details of the Carestream compliance approach and timeline.

GS1 GTIN:

- GS1 General Specifications – www.gs1us.org/healthcare
- GS1 Healthcare US: Healthcare Supplier Tool Kit - Global Trade Item Number (GTIN) – www.gs1us.org/healthcare
- GTIN Allocation Rules – www.gs1us.org/healthcare

Commercial Transactions

- How EDI accommodates GS1 GLN & GTIN – www.gs1us.org/healthcare

US FDA UDI:

- U.S. FDA: Final Rule - Unique Device Identification System: September 24, 2013 – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- U.S. FDA: Global Unique Device Identification Database (GUDID) - Guidance for Industry and Food and Drug Administration Staff: June 27, 2014 – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- U.S. FDA: Unique Device Identification System: Small Entity Compliance Guide - Guidance for Industry and Food and Drug Administration Staff: August 13, 2014 – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- U.S. FDA: Unique Device Identifier System: Frequently Asked Questions, Vol. 1 - Guidance for Industry and Food and Drug Administration Staff: August 20, 2014 – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- U.S FDA: Public Health Service Act http://www.fda.gov/regulatoryinformation/legislation/ucm148717.htm

GS1:

- GS1 US Healthcare Implementation Guideline: Using the GS1 System for U.S. FDA Unique Identification (UDI) Requirements – www.gs1us.org/healthcare
- GS1: GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guide – www.gs1us.org/healthcare
- GS1 US Healthcare: GTIN Attribute Mapping for FDA Global Unique Device Identification Database (GUDID) – www.gs1us.org/healthcare
- GS1 US Healthcare: Medical Device Brand Owner Guide – Transitioning to GS1 Standards In the U.S. for UDI – www.gs1us.org/healthcare