

## GLOBAL STANDARDS GLOSSARY

### > A Guide from GHX

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#### D

**DI:** Device Identifier ([www.gs1.org](http://www.gs1.org))

**DPM:** Direct Part Marking (DPM) provides a permanent marking solution that ensures readability throughout the life of products, even when subjected to harsh environments during the manufacturing process ([www.motorola.com](http://www.motorola.com)).

#### E

**EHR:** The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter — as well as supporting other care-related activities directly or indirectly via interface — including evidence-based decision support, quality management, and outcomes reporting ([www.himss.org](http://www.himss.org)).

#### H

**HL7 SPL:** Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information ([www.fda.gov](http://www.fda.gov)).

#### F

**FDAAA:** Food and Drug Administration Amendments Act ([www.fda.gov](http://www.fda.gov))

## G

**GAO:** The U.S. Government Accountability Office (GAO) is known as "the investigative arm of Congress" and "the congressional watchdog." GAO supports Congress in meeting its constitutional responsibilities and helps improve the performance and accountability of the federal government for the benefit of the American people ([www.gao.gov](http://www.gao.gov)).

**GHTF:** The Global Harmonization Task Force (GHTF) was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems ([www.ghrf.org](http://www.ghrf.org)).

**GMDN Classification code:** Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury in humans ([en.wikipedia.org](http://en.wikipedia.org), [www.gmdnagency.com](http://www.gmdnagency.com)).

**GSDN:** Global Data Synchronization Network ([www.gs1.org](http://www.gs1.org))

**GS1:** GS1 is an international not-for-profit association dedicated to the design and implementation of global standards and solutions and to improving the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world ([www.gs1.org](http://www.gs1.org)).

## H

**HIBCC:** The Health Industry Business Communications Council (HIBCC) is an industry-sponsored and supported nonprofit organization. Its primary function is to facilitate electronic communications by developing appropriate standards for information exchange among all healthcare trading partners ([www.hibcc.org](http://www.hibcc.org)).

## M

**MMIS:** Medicaid Management Information System (MMIS) is an integrated group of procedures and computer processing operations ([www.cms.gov](http://www.cms.gov)). Among the benefits of MMIS is real-time processing of claims, weekly financial cycle. Providers can submit their claims and follow-up immediately if they're being paid. If there is no problem, the claim will be paid that week ([www.georgia.gov](http://www.georgia.gov)).



## N

**NDC:** Products are identified and reported using a unique, three-segment number called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA inputs the full NDC number and the information submitted as part of the listing process into a database known as the Drug Registration and Listing System (DRLS) ([www.fda.gov](http://www.fda.gov)).

**NHRIC:** National Health Related Items Code (NHRIC) is a system for identification and numbering of marketed device packages that is compatible with other numbering systems such as the National Drug Code (NDC) ([www.hipaaspace.com](http://www.hipaaspace.com)).

## P

**PHR:** The term “Personal Health Record (PHR)” has been applied to both paper-based and computerized systems; however, current usage usually implies an electronic application used to collect and store health data. It is important to note that PHRs are not the same as Electronic Health Records (EHRs). The latter are software systems designed for use by healthcare providers. Like the data recorded in paper-based medical records, the data in EHRs are legally mandated notes on the care provided by clinicians to patients. There is no legal mandate that compels a patient to store personal health information in a PHR (<http://en.wikipedia.org>).

**PI:** Production Identifier (PI)

**Premarket Risk Class 1, 2 and 3:** Classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk ([www.fda.gov](http://www.fda.gov)).

## R

**RFID:** Radio Frequency Identification ([www.aimglobal.org](http://www.aimglobal.org))

## U

**UDI:** Unique Device Identification ([www.fda.gov](http://www.fda.gov))

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