



HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL

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HIBCC ACCREDITED BY U.S. FDA AS UDI ISSUING AGENCY

PHOENIX, AZ (December 26, 2013) - The U.S. Food and Drug Administration (FDA) today announced HIBCC's accreditation as an Issuing Agency for Unique Device Identifiers (UDIs).

In the final rule released in September of 2013, FDA identified the global HIBC Supplier Labeling Standard (SLS) as an appropriate data format for UDI. The HIBC SLS has also been recognized by the European Commission in their developing regulation on device identification, as well as by the International Medical Device Regulators Forum (IMDRF).

After today's announcement, HIBCC President and CEO, Robert A. Hankin, Ph.D. commented, "The UDI initiative is fundamental to enhancing patient safety and cost containment measures. HIBCC is pleased to be serving as an FDA-accredited Issuing Agency to assist the industry in efficient and comprehensive UDI implementation."

In support of the UDI initiative, HIBCC has developed the [UDI Resource Center](#), which includes numerous implementation documents, the LIC application, and an on-line 'UDI Generator'. For additional information, or to register for a HIBC LIC, please contact the HIBCC office at: 602.381.1091 or visit www.HIBCC.org.

HIBCC is an industry-sponsored, Standards Development Organization (SDO) founded in 1983 to develop a healthcare-specific standard for the unique identification of medical products. HIBCC is accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and is recognized by the International Organization for Standardization (ISO). Our efforts are supported worldwide by affiliate offices in Europe and Asia Pacific. Additional information regarding the HIBCC organization can be accessed from the HIBCC website at: www.hibcc.org.

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