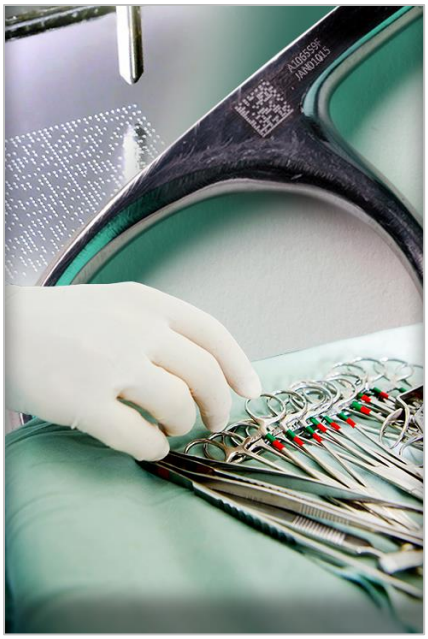
FOR IMMEDIATE RELEASE:

Microscan Webinar Offers Guidance for Applying and Verifying Permanent Marks on Medical Devices for FDA UDI Compliance



RENTON, WA, June 15, 2016 — Microscan, a global technology leader in barcode, machine vision, verification, and lighting solutions, announces that it will host a live educational webinar titled "Direct Marking for UDI Compliance" – a review of the FDA's draft guidance and best practices for permanently marking and verifying UDI codes on medical devices sold in the United States. The presentation and live question-and-answer session with Microscan UDI expert Barbie LaBine are free to attend and will take place during a 30-minute web session on Wednesday June 29 at 10 A.M. PDT (Seattle) / 1 P.M. EDT (Boston).

A final Unique Device Identification (UDI) rule published by the FDA on September 24, 2013, began the countdown for medical device manufacturers who distribute and sell medical devices within the United States (regardless of manufacturing country) to meet strict deadlines for product marking and serialization. The next deadline in the FDA's regulation is September 24, 2016, and it requires that all class III medical devices (such as pacemakers, heart valves, implants, and other "high risk" devices) bear a UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. Since reprocessing (for example, sterilization or other processes) may cause devices to become separated from their original UDI-compliant labels and packages, direct marking is necessary to ensure that a UDI is permanently available throughout the device's distribution and use in case adverse events (such as a product recall) require devices to be identified in the field and traced back to their original manufacturers.

Direct part marking (DPM) is not a new concept in industrial manufacturing like automotive or electronics assembly, where parts may easily become separated from identifying information that is not permanently affixed due to excessive handling or harsh environmental factors (varying temperatures, vibrations, or exposure to liquid or debris). However, the process of marking devices with permanent codes may be relatively new territory for medical device manufacturers. For these companies regulated by UDI, not only do code generation and printing techniques need to be updated to incorporate UDI on packaging and labels, but an investment must also be made to add marking methodologies to the manufacturing process to implement permanent UDI marks. The FDA offers draft guidance on device marking, but without finalized requirements, even barcode standards organizations like GS1 and ISO do not have precise parameters for applying manufacturer codes or verifying UDI for accuracy in every marking condition.

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As agencies and solution providers work to define best practices for UDI permanent marking and verification, manufacturers can best prepare for their compliance deadlines by arming themselves with knowledge from current documentation about UDI requirements and DPM solutions. Microscan's experts have reviewed draft guidance for FDA UDI direct marking to understand existing parameters and how to define best practices and solutions for customers facing upcoming deadlines. This research, combined with over 30 years in the business of reading and verifying DPM, are the basis for Microscan's latest webinar offering guidance on direct marking for UDI compliance, with answers to common questions.

Barbie LaBine, Training Coordinator at Microscan, leads this webinar on permanent marks, marking methods, and verification solutions, with a live Q&A session following the presentation to answer attendee questions regarding UDI direct marking and verification. A Certified GS1 Standards Professional, LaBine has provided training to global medical device manufacturers on UDI compliance and UDI code and label verification for the past two years. LaBine comes to Microscan from the industry-leading barcode verification systems manufacturer Label Vision Systems, Inc., (acquired by Microscan Systems, Inc., in August 2015), and now offers a range of training on Microscan technology and applications.

To learn more and to register for the live webinar on June 29, "Direct Marking for UDI Compliance," visit the Microscan website at: http://bit.ly/22Kk2h2.

About Microscan
Microscan is a global leader in barcode reading, machine vision, and verification technology serving a wide range of automation and OEM applications. Founded in 1982, Microscan has a strong history of technology innovation that includes the invention of the first laser diode barcode scanner and the 2D symbology Data Matrix. Today, Microscan remains a leader in automatic identification and inspection with extensive solutions ranging from barcode reading, tracking, and traceability up to complex machine vision measurement, guidance, symbol verification, and print quality grading.

As an ISO 9001:2008 certified company recognized for quality leadership in the U.S., Microscan is known and trusted by customers worldwide as a provider of quality, high precision products. Microscan is a part of Spectris plc, the productivity-enhancing instrumentation and controls company.

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