ZEBRA

Unique solution for unique device identifier

THE BEST ANSWER FOR MANUFACTURERS OF MEDICAL DEVICES TO NEW LABELLING REQUIREMENTS

COMPLETE SOLUTION
PROVEN TECHNOLOGIES
FLEXIBLE OFFERING

Complete, proven, flexible solution for manufacturers

Ensure UDI compliance

Class I, II and III medical devices distributed in the United States must carry a unique device identifier (UDI) to meet the requirements of the Food and Drug Administration (FDA). This legislation is soon to become a global requirement.

NO UDI? NO BUSINESS...

The compliance dates for this regulation are phased: class III device requirements came into effect on September 24th 2014 and the rest are being introduced in categories within stages until September 24th 2020 by which time all classes will be covered.

- Class III devices: able to support or sustain human life and/or to prevent impairment of human health – eg. pacemakers, automated external defibrillators
- Class II devices: requiring higher-than-normal checks to ensure safety and effectiveness eg. powered wheelchairs, infusion pumps
- Class I devices: not intended to support or sustain human life nor to prevent impairment of human health – eg. elastic bandages, examination gloves

Medical device product identification labels:

- Maintain compliance
- Ensure brand consistency
- Improve operational efficiency
- Support business growth.

UDI IN MANUFACTURING

We provide a comprehensive solution that will enable compliance with UDI regulations smoothly, quickly and comprehensively. Our unique offering includes the print device, scanner, label design software, global compliance tools and thermal supplies that can:

- Withstand sterilisation
- Withstand cleaning agents used in hospitals
- Last the life of product until its disposal
- Meet UL* standards.

*Underwriters Laboratories

WE BRING TOGETHER THE LEADERS IN ID COMMUNICATIONS TO PROVIDE THE MOST COMPREHENSIVE MANUFACTURING SOLUTION AVAILABLE.

Complete, proven, flexible solution for healthcare providers

UDI IN HEALTHCARE

UDI needn't just be a legal requirement – you can make it an opportunity for continuous improvements in both healthcare and manufacturing for overall patient safety and tracking and traceability of products:

- Report, review and analyse adverse events so problem devices can be identified and corrected more quickly
- Reduce medical errors by enabling healthcare professionals and others to identify a device rapidly and precisely, obtaining important information about its characteristics
- Enhance analysis of devices on the market
- Ensure brand integrity for manufacturers.

I ♥ RULES

TURN COMPLIANCE INTO OPPORTUNITY

As a leading provider of track and trace technology to healthcare and manufacturing providers, Zebra is uniquely positioned to meet the UDI challenge so you can:

- Improve asset visibility
- Improve recall effectiveness
- Provide complete transparency
- Enable better continuity of care
- Improve patient safety
- Eliminate manual data entry and so reduce errors.

ZEBRA'S SOLUTIONS SETS ARE TESTED, CERTIFIED AND RECOMMENDED BY LEADING HEALTHCARE PROVIDERS.

Solution components

- Printers
- Scanners
- Specialised labels
- Networking
- Software provider partnerships
- GS1 experience
- Mobile computing

CONTACT US FOR MORE INFORMATION OR TO SCHEDULE A DEMONSTRATION OF OUR UDI SOLUTIONS OFFERING.

WWW.ZEBRA.COM/UDI

FOR ADDITIONAL INFORMATION, VISIT:
WWW.ZEBRA.COM/UDI

ZEBRA

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