Are Your Labels Compliant with European MDR?

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Label Compliance with the New European Medical Device Regulations (MDR)

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Live Q&A Following the Presentation
To ask a question during the following presentation, please use the Questions window on the right side of your screen. Questions will be queued and answered after the presentation.
Today’s Agenda

USDM
- European MDR/IVDR Regulations, what do we know so far?
- What about NHS UK UDI Compliance?
- FDA UDI vs EU MDR, what are the similarities and differences?
- What do you need to do right now to prepare?

NiceLabel
- How digitally transforming the labeling process and implementing a label management system ease compliance with both FDA UDI as well as EU MDR

Microscan
- What about label verification? Just reading a barcode is not enough
- Comparison of 100% vs. random barcode and print quality inspection
- Is there an easy solution for label verification/print quality inspection?
European MDR/IVDR Regulations –
What do we know so far and
What do you need to do now to prepare
About USDM Life Sciences

- USDM Life Sciences is a global life science and healthcare services company
- Strategy and compliant technology solutions to regulated industries
- Accelerate innovation and maximize productivity
European MDR/IVDR Regulations, what do we know so far?

- **MANY** changes to how devices are regulated; classification changes.
- Introduction of UDI System “based” on IMDRF (International Medical Device Regulators Forum) guidance.
- Distributor/importer assumes obligations if markets a device under his name... reprocessor of SUD is considered the manufacturer
- Importers + distributors have new responsibilities for distributed devices
European MDR/IVDR Regulations, what do we know so far?

- Traceability by economic operators + health institutions for class III implants (one up/one down).
- For active implantable devices – serial number; others lot or serial.
- Label requires time for using/implanting device safely – as year & month; when no indication of this date – the date of manufacture.
- For “sterile packaging” – BOTH are required.
What about NHS UK UDI Compliance?

- UDI “like” – “commercial” mandate – “based” on MDR/IVDR
- Applies to all “regulated” devices – though timelines and rules unclear – will eventually apply to ALL products (anything you sell to NHS)
- GS1-centric – GTINs, GLNs (UK location manager); GDSN for product master data – and PEPPOL for orders and invoices.
- “... after review required by the EU UDI legislation, DH has decided that dates specified in the DH timeline will remain unchanged...”
What about NHS UK UDI Compliance?

- MDR/IVDR allows Class I/IIa SUDs UDI not on label but on next level of packaging; DH requires Class IIa devices have UDI on “unit of use” label

1. Allocate GLNs to locations;
2. GTINs to devices;
3. Publish meta-data to GDSN;
4. Publish price data to GDSN;
5. Label to carry GTIN (DI only);
6. Label to carry GTIN with PIs;
7. Receive order from NHS;
8. Send invoices to NHS;
9. Receive orders w/GTIN+GLN;
10. Send invoices w/GTIN+GLN
FDA UDI vs EU MDR - similarities and differences?

- Based on GHTF/IMDRF UDI guidances; Global issuing agencies
- UDI assigned/marketed with AIDC+HRI (neutral) on labels & packages
- Accessories, systems/configurable devices, procedure packs/convenience kits
- “Combination products” – if regulated as device – needs UDI
- UDI for SaS/SaMD in embedded screen and label/physical media
FDA UDI vs EU MDR - similarities and differences?

- Shipping containers, custom and investigational devices – exempt
- Retail/POS do not require PIs in UDI (US class I, others by request)
- Reusable devices need “direct mark” (permanent) UDI on device
- UDI for implants **MUST** be identifiable prior to implantation.
- UDI Database – submit (static) core data attributes for each device
- Barcode verification
What do you need to do right now to prepare?

- Develop complete SKU list of all devices – and ACCESSORIES
- Review classification rules (when label/package UDI needs to be applied)
- Determine devices reused & reprocessed – subject to additional DM
- Organize device master data (location/ownership/rules) – UDI Database due 26 May 2020/2022 (MDR/IVDR)
- Determine/document relationships (e.g., OBL, contract manufacturers, importers, distributor) – and applicable UDI responsibilities
What do you need to do right now to prepare?

- Review current labels and packages to determine where/how UDI applied
- Develop appropriate barcode implementation strategies; verification
- Review current SOPs and systems for inclusion of UDI
- Develop a UDI program and project plan
Thank You!

Web: usdm.com
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Transform your labeling while complying with EU MDR
Medical device companies that transformed
Elements of a GS1 DataMatrix UDI label
Lessons learned from these companies:
Quality  Speed  Efficiency  Cost
Three pillars of a label management system

MANAGE

- Traceability
- Label variations
  - Document version control
- Printers & queues
  - Approval workflows
- Security & role based access
- Digital label catalog

PRINT

- Centralize & deploy web printing applications
- Integrate printing from existing business systems

DESIGN

- Design dynamic & universal labels
- Configure printing forms to streamline manual printing processes

Quality Assurance

Data Accuracy

Agility
Document Storage

Save and access your label templates and associated files in one location.
Document Storage
Save and access your label templates and associated files in one location.

Change workflow step (UDI-GS1-linear.nlbl)

Current step: Draft
Next step: Request approval

Comment:
Please approve the changes. I have modified the format of the date and removed "dd".
### Document Storage

Save and access your label templates and associated files in one location.

#### File revision history (UDI-GS1-linear.nlbl)

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**Items:** 13 (562 KB)
Transform while complying with EU MDR - printing

Integrated printing

Forms printing
7 Key takeaways

Digitally transform your labeling to:

1. Free up IT resources and empower business users
2. Integrate labeling with your master data and eliminate manual data entry
3. Digitalize quality assurance process
4. Create a fully transparent label process
5. Establish consistent labeling across all sites
6. Recognize the level of collaboration needed across company divisions
7. Increase agility and get faster time-to-market
Where to Learn More

- LiNA Medical case study

- White Paper: “EU MDR and IVDR: Uncovering Hidden Cost Savings While Complying with Device Traceability and UDI Requirements”
  - https://www.nicelabel.com/white-papers/eu-mdr-white-paper


- NiceLabel medical device micro-site
Thank You

www.nicelabel.com/medical-devices
Label Verification and Print Quality Inspection
Microscan Overview

- Founded in 1982 by an entrepreneur in barcode reading technology – first to use a laser diode to decode a barcode
- 35 years of innovation in barcode, machine vision, and verification
- Recently became a business unit of Omron Corporation, $8.5B global provider of technology products and solutions
- Headquartered in Seattle, Washington, USA
- R&D Center in Nashua, New Hampshire, USA (Siemens acquisition, 2008)
- Manufacturer of leading systems in print quality inspection and barcode verification systems (Label Vision Systems (LVS®) acquisition, 2015)
What about label verification?
Just reading a barcode is not enough

- Verification is an objective, precise standardized measurement of the quality of a barcode symbol. It is a predictor of how well a code will be able to be read throughout its life cycle.

Without verification, bad barcodes are not identified until they are unreadable. By the time a bad barcode is identified, several poor-quality barcodes may have already escaped down the line.

With verification, bad barcodes are prevented from being applied to the product, eliminating the chance for future failures.
Comparison of 100% vs. random barcode and print quality inspection

- The verification test specifications are defined in the following globally accepted standards:

  ✓ ISO/IEC 15415 and 15416 - Barcode print quality test specifications, as applicable.
  
  ✓ ISO/IEC 15426-1 and ISO/IEC 15426-2 - Barcode verifier conformance specifications, as applicable.
UDI and Barcode Verification

- Checking of barcode content, format and quality
  - Need to deconstruct barcode to confirm correct and correctly formatted data
  - Need to check print/mark quality to confirm that codes will be readable

- FDA UDI requires that medical device labelers will follow the issuing agency’s rules and guidelines
  - All issuing agencies require barcode quality of grade C or better
  - In the case of GS1, these are specific. “An unreadable bar code is the same as a missing bar code, which would mean non-compliance”
  - EU MDR?

http://www.gs1.org/docs/barcodes/1D_Barcode_verification_implementation_guideline.pdf

System Approach to Verification and Label Inspection

- Off-Line verifier used for template initial check of data structure, printing quality
- In-line verifier used for 100% production monitoring and performance data collection
Microscan LVS® 7510 Inspection Capabilities

- Confirms the accuracy of the printed label image to user defined levels ensuring quality standards are met
- No slowdown in printing speeds – inspects at 250mm/sec (10”/sec)
- IQ/OQ/PQ validation package available

Benefits:
- Identifies Defects Immediately
- Compliance to FDA and EN regulations for label inspection
- Eliminates Fines and Disputes
- Reduces Rework
- Controls Waste
- Avoids Liability
- Data Management

Features:
- 1D and 2D barcode Verification and grading to ISO 15415/15416
- GS1 identifier check
- Master-to-Label Comparison (Blemish Detection)
- Optical Character Recognition
- Optical Character Verification
- Number Validation
- Data & Code Matching
How Does LVS-7510 In-Line Inspection Work

- Inspection System is integrated by Microscan into the thermal transfer printer, such as Zebra ZT600, Printronix T8000 series printers
- Inspection template defines what information should be inspected
- Inspection system template “loaded” and ready for print job that is then initiated by the Label Management software
- If a printing error occurs (print fault) the printer stopped and an alarm is sent to a light tower
  - Manual operator inspection of the defective label
  - Automated overstrike of the defective label
- Real time display of error and label run statistics on HMI
- Inspection results are archived and optional exported into another database or printed
Label Data Analysis and Archive

- Convenient and powerful tool to ensure that 100% label inspection has been performed
- Provides insight to top causes of label print errors

![Bar chart showing Medi-Device Label Errors]

- Printing Blemish
- Incorrect Data
- Illegible Data
- Barcode Grade ≤ 1.5

![Bar chart showing Production Plant XYZ Printing Errors]

- June
- July
- August
- September
Summary

- Barcode Verification and Print Quality Inspection are an important part of an overall Label Compliance and Management Program.
- New solutions that allow for 100% print quality inspection with no compromise on production throughput are available.
- A combination of in-line and off-line inspection and verification is a best practice for compliance to standards such as EN ISO 13485 Medical devices – Quality management systems/ Requirements for regulatory purposes, FDA UDI, and EU Medical Device Regulations.

- See Microscan at EU MDR & IVDR show, Orlando Dec. 5 - 6

http://www.mdrivdr.com/mdr-ivdr-compliance/
Thank You!

Any Questions?
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