Unique Device Identification
A Manufacturers View

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Why UDI Guidance now?

UDI Guidance is an important milestone for a better, unambiguous MedDev identification to improve patient safety!

Quality
- product itself
- identification
- impact on syst. outcome

Global business
- cross-border trade
- multilingual labeling

Country-specific deviations
- counterproductive
- supply chain efficiency?

Costs issue
- implementation efforts
- secure investments

Only a globally accepted UDI Guidance will have positive impact!
Importance of the Implementation Sequence

UDI becomes law

+ 1 year
Step 1
• Highest Risk Class
  • review results 1
  • system adjustments (?)

+ 3 years
Step 2
• Medium Risk Class(es)
  • review results 2
  • system adjustments (?)

+ 5 years
Step 3
• Lowest Risk Class
  • review results 3
  • system adjustments (?)

Both in parallel: AIDC + UDID entries

Complexity will increase step-by-step
- diversity of MD product portfolio, no. of products, UDID entries, etc.

REVIEW!
achieved results (experiences) need to be analyzed before the next step starts
Key Challenge: Implementation timelines

Why do we need 'so much' time?

UDI regulations will mainly focus on
AIDC marking of the consumption unit level!
( primary pack or product itself)
Key Challenge: Primary Pack

**technical framework**

- limited space means → small carriers + high data density
  - e.g. DM size: 6x6 - 10x10 mm
- production/packaging line speed
  - speed reduction by an additional print not acceptable
- packaging material (Tyvek, coated/uncoated paper, label, …)
- printing technology (inkjet, thermo transfer, etc.)
  - often replacements necessary!

variable data within the AIDC carrier = in-line printing!
Key Challenge: Primary Pack

quality issues

- DM quality verification: ISO/IEC 15415 (final grade 1,5)
- absorptive / translucent paper in use
- only validated ink permitted
  - impact on contrast between ink and paper?

DM through the camera of the verifier

our experience:
verifier fails / low-cost image scanner reads
Key Challenge: Multilingual labeling

AIDC Carrier
- globally harmonized data content
- technology neutral

UDI is an additional labeling requirement!

One product presentation for many markets (supply chain efficiency)

sample 'primary pack'

sample 'secondary pack'

16 languages

26 languages
Key Challenge: Direct Part Marking

- no problem at bigger devices / machines
  - metal plates
  - labels / stickers
  - tags
  - ...  

- but significant technical efforts at many other reusable products
  - product characteristics
  - carrier size
  - DPM technology
  - durability
  - ...
Fact: AIDC implementation is time consuming

- technical feasibility studies
  - pack. material, print technology, ink, impact on production speed, …
- investment planning + release
- new hardware / software (for in-line printing)
- label artwork / packaging paper
  - redesign to have space for AIDC carriers
- technical engineering efforts
  - HW installation, lines 7 days/24h in use, …
- perform test trials
- measurements to fulfill AIDC carrier quality requirements
  - 100% control by camera systems vs. sample checks
  - e.g. in full-autom. pack. lines, how to handle faults, sort-out/bypass
  - define internal globally harmonized test methods
- process qualification and validation
- documentation
  - drawings, process descriptions, notified bodies, …
- …

cross-functional project teams + top-management support
Key Challenge: UDI Database

Set of global core elements:
• Packaging Hierarchy (unlimited no.), per pack. level
  • Device Identifier / Unit of Measure / Quantity
• Manufacturer Name
• Manufacturer Contact Information (address, email, phone)
• Nomenclature (e.g. GMDN code)
• Nomenclature Term (e.g. GMDN term)
• Trade Name
• Device Model Number (REF No./catalog no.)
• Controlled by (e.g. expiry date, manuf. date, lot no., serial no., …)
• Size/Volume/Length/Gauge… (clinically relevant characteristics)
• Product Description (additional clinically relevant info.)
• Special Storage/Handling Conditions
• Labeled as ‘single use’
• Sterility / Package sterile
• Need to be sterilized before use
• Restricted number of reuses
• Containing Latex
• Authorized Representatives (list of countries and addresses)
• License / marketing Authorization (e.g. registration no.)
• URL for additional information
• Critical warnings or contraindications

Manufact. need to ensure:
• data availability in e-format
• data quality / accuracy
• up-to-dateness
• proper processes
  (data maintenance + upload to 3rd-party)

UDID
MD identification + labeling
Key Challenge: UDI Database

Manufacturers requirements:
- as less UDID’s as possible
- ideally a ‘single point of entry’ for data upload?
- avoid regional add-ons?
- clarity regarding DB design / techn. details
→ we are able to bring in our knowledge!
Fact: UDI Implementation will be complex

AIDC: many production lines affected at the same time
→ Centers of Excellence concepts

UDID: processes for data collection, up-to-dateness + upload
→ many people need to be sensitized!
UDI is the foundation, leading to improved processes for...

- Reimbursement
- Traceability
- Post Market Surveillance
- Electronic Health Record
- Product Recall
- Cross Border Trading
- Anti-counterfeiting
- Research
- Data Quality
- Authentication

UDI creates transparency, improves processes, increases efficiency and makes isolated systems interoperable.
UDI will bring great benefits for:

- **PATIENT SAFETY**
- **IMPROVED VIGILANCE & MARKET SURVEILLANCE**
- **GLOBAL TRADE**

BUT it is essential that

- A pragmatic (risk-based) approach is adopted
- Healthcare providers are fully resourced to respond
- Regional authorities co-operate to ensure a truly **GLOBAL** and **HARMONISED UDI** approach

→ otherwise much time and resources would be wasted!
Thank you very much for your attention!

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