EU Regulations 2017/745:
How will the glove industry be affected?

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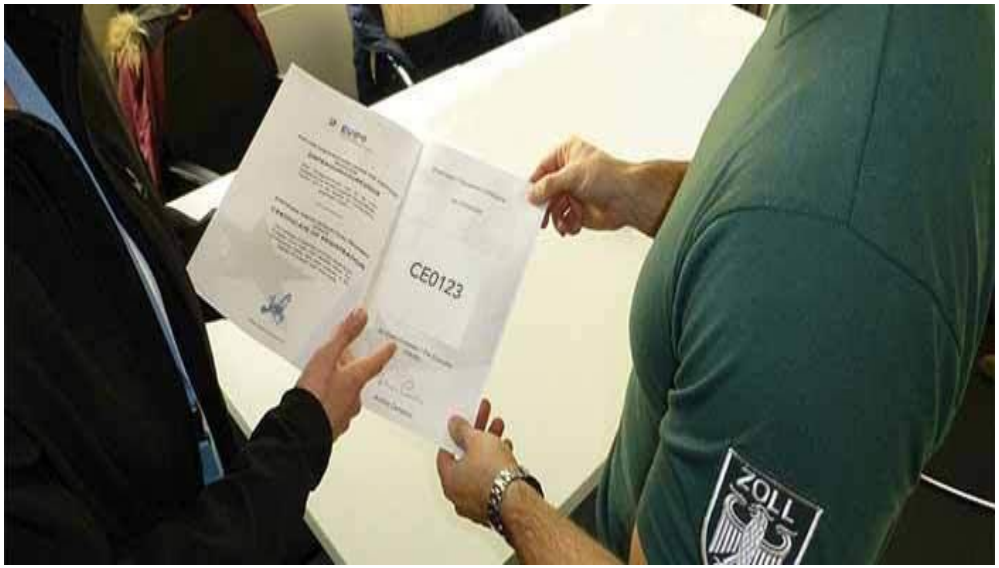

The Medical Devices Regulations

- entered into force May 25 2017
- will become fully applied May 26 2020
- certain regulations therein will be enforced for all devices (including legacy devices) BEFORE May 26 2020

Manufacturers of medical gloves classified as Class I, Class I sterile and Class IIa medical devices will be affected.

Non sterile Class I exam gloves: not later than May 26 2020

Other classes of Legacy Devices:
if an MDD cert expires after May 26 2020, then it must be replaced by MDR but no later than May 26 2024. **No significant changes in the interim.**

A SAMPLE OF MDR REQUIREMENTS: (a.k.a Tip of the iceberg)

- Unique Device Identification system
- Common Specifications
- Post market controls
- Adverse event reporting (Article 87) and Trend reporting (Article 88)
- Registration
- The Case for distributors and importers who makes available a device under its name
- Person responsible for regulatory compliance
- European Database on medical devices (EUDAMED)
- Other concerns

The opinions expressed in this presentation are solely that of the Speaker

Unique Device Identification system (Article 27) and Basic UDI (Article 29)

- Not similar to US UDI
- Assignment by designated entities
- Device and Production Identifiers to be on the label/packaging of device
- Basic UDI required for device registration and changes
- Timelines depend on class of devices

Common Specifications (Article 9)

- Product performance requirements for conformity to General Safety and Performance Requirements
- To complement (or serve as) harmonized standards e.g. when unavailable or insufficient
- Subject to changes (Article 10.9)

Post market controls (Chapter VII)

- Requires active and systematic approach (Article 83)
- Periodic safety Update report for Class IIa (Article 86)
- Post market surveillance report for Class 1 (Article 85)

Adverse event reporting (Article 87) and Trend reporting (Article 88)

- Current specifications adopted from the Meddev 2.12/1 Rev 8
- Specification of reporting timelines e.g.
  - Not later than 2 days for serious public health
  - Not later than 10 days in the event of death and unanticipated serious deterioration
  - Not later than 15 days for serious events
- Trend reporting now part of regulations

Registration

- Device registration (Article 29)
- Economic operators: assignment of Single Registration Numbers (Article 31)

The Case for distributors and importers who makes available a device under its name (Article 16)

- Situation where the `actual' manufacturer is not indicated
- End of Private L:abel Manufacturing conformity assessments?

Person responsible for regulatory compliance (Article 15)

- Required for both manufacturers and authorized representatives
- Device conformity, technical documentation, post market surveillance, reporting obligations etc.

European Database on medical devices (EUDAMED) (Article 33)

- Scope:

Registration of devices

UDI database

Registration of economic operators

Vigilance and post market surveillance

Other concerns

E.g. What about gloves classified higher than Class IIa?

- Consultation (for combination devices)
- Summary of Safety and Critical Performance

Conclusions:

- Comprehensive new requirements introduced
- New or revised procedures
- Profound changes expected including labelling
- Technical documentation (Clinical evaluation)

Questions?

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