

ISSUE 7: IN-SERVICE BRIEF Medical Device Packaging

Medical devices are manufactured and packaged depending on their intended use, how they will be transported, how they will be handled, and stored in their final destination. It is unlikely for a healthcare worker to think about packaging needs, but manufacturers have many considerations including not only protecting the device itself but also adhering to multiple jurisdiction requirements included with labeling.



Curved fingers
smooth surface.
Гладкая поверхность



Meets
ISO 10282 requirements.



Example of labeling
requirements



MDD 93/42/EEC (Class IIa),
PPE 89/686/EEC (Cat. III)



Example of internationally
recognized standards



Example of product barcode
Dates are displayed in
year/month/day

How medical devices are packaged depends on:



Type and Size of Device



Intended Use



Transportation



Handling



Storage Conditions



Expiration Date

Packaging can perform a function as simple as separating products into individual or multiple units and as complex as providing specialized environments for highly perishable items.

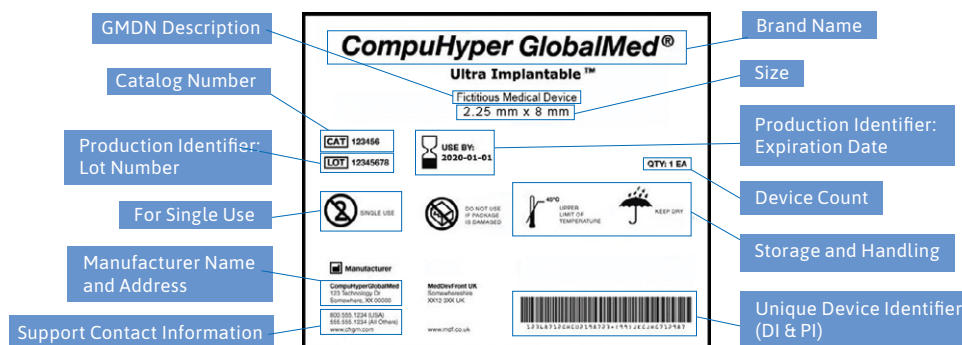
Packaging during manufacturing needs to comply to requirements of multiple jurisdictions including:

- Regulatory bodies
- Transportation services
- End users
- Distributors
- Stores
- Waste disposal

Medical Device Packaging to Consider

- Sterilization process
- Environmentally friendly
- Waste disposal cost
- Compact size and smaller size packaging
- Weight of package
- Traceable
- Non-toxic, non-leaching and odorless
- Capable of being presented aseptically

Example of Device Labeling¹



GUDID Attributes Mapped to a Fictitious Medical Device Label

References:

1. U.S. Department of Health and Human Services Food and Drug Administration. Center for Devices and Radiological Health. Centre for Biologics Evaluation and Research. GUDID – Guidance for Industry and FDA Staff. June 27, 2014.

➔ For more information, visit www.ansell.com/AnsellCARES

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Ansell Surgical Gloves

State of the art medical device packaging

Smaller Pouch – requires less space, less environmental waste, more products per box, and proven to reduce risk of inadvertent contamination in transfer process.

Dispenser Box – versatility with shelving configuration (vertically or horizontally) to reduce space requirements, more gloves per box to reduce number of times it must be changed.

Lightweight Package – easy to move, less risk of ergonomic handling and transportation injury. Less environmental waste.

Important Tip

Smaller sized cartons, dispensers and/or pouches all contribute to reductions in the amount of and cost of generated waste.