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Meeting The Language Requirements of the EU's Medical Device Regulation

Meeting The Language Requirements of the EU's New Medical Device Regulation

Presented by:

UNITED LANGUAGE GROUP

EMERGO by UL

Ronald Boumans
Emergo
Senior Global Regulatory Consultant

United Language Group is one of the largest Language Solutions Providers in the world, providing smart, seamless and secure language solutions that help businesses win in the global marketplace. United Language Group envisions a world in which language is no longer a barrier, and helps global clients turn language translation and interpreting into a competitive advantage.

Disclaimer

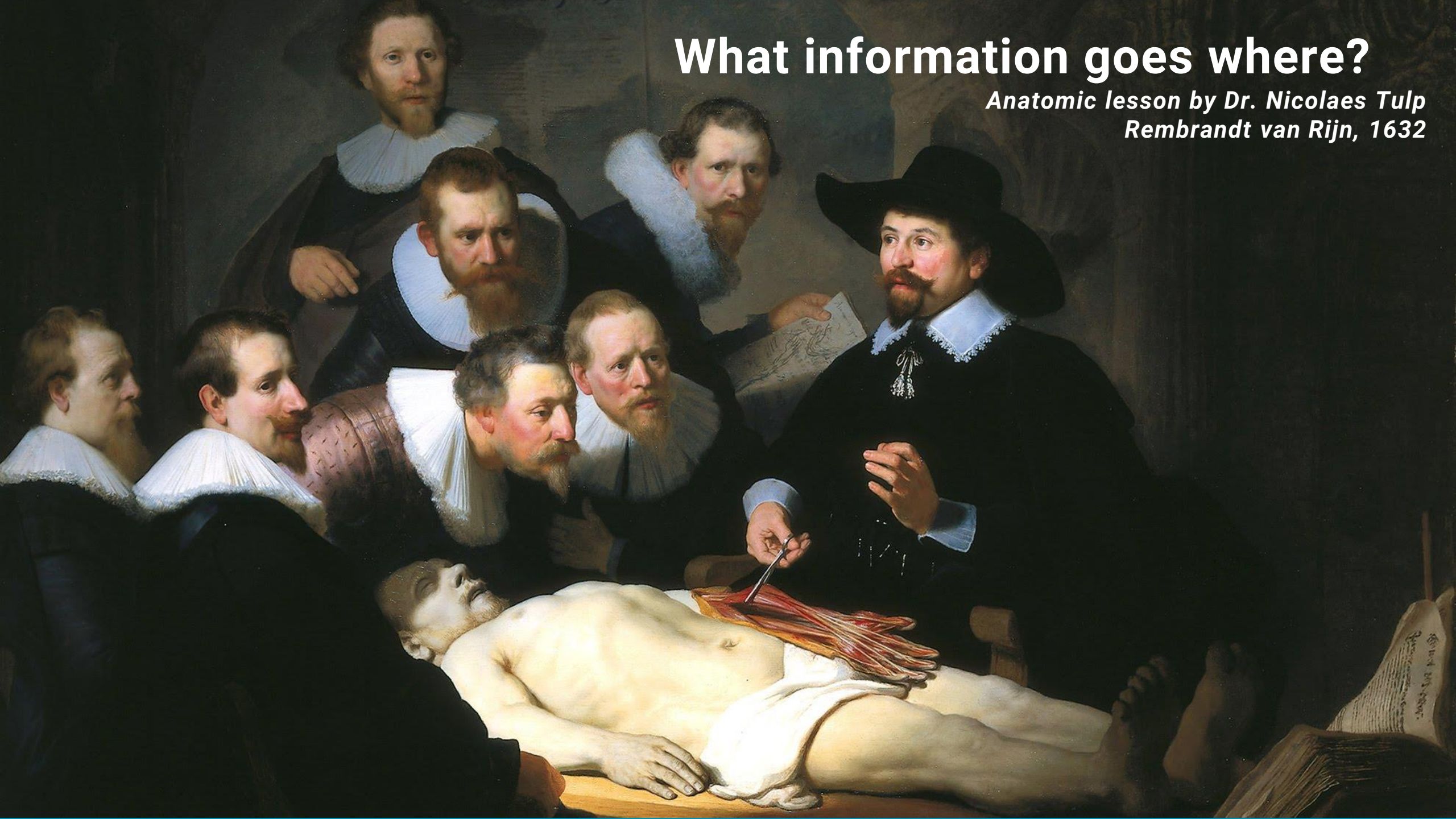
Garden of Earthly Delights,
Hieronimus Bosch, around 1500

Agenda

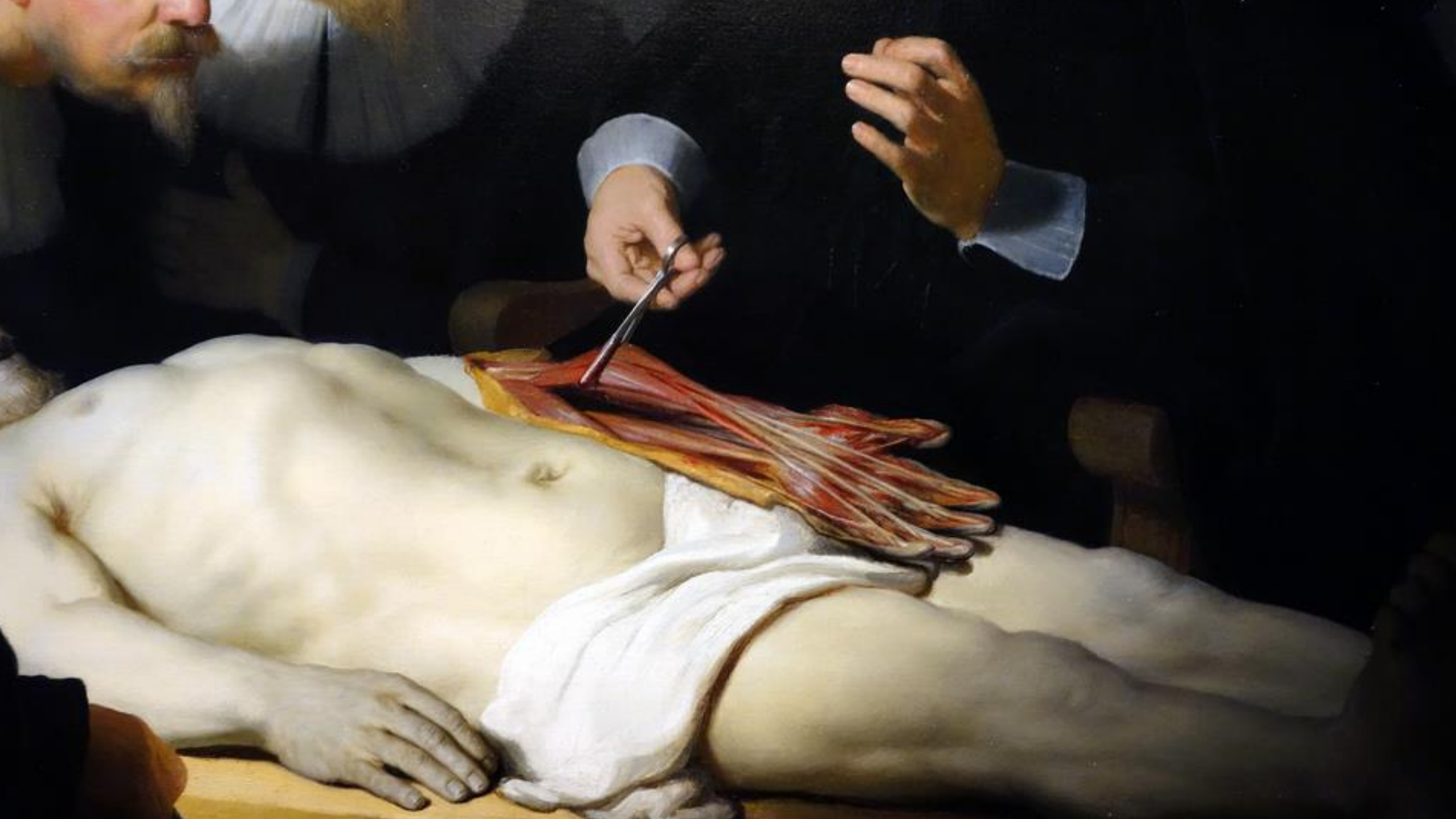
Language-specific labeling requirements under the MDR and IVDR

- What Information Goes Where?
- General Principles Of Labelling Language In Europe
- Risks And Opportunities In Labelling Design

What information goes where?



Anatomic lesson by Dr. Nicolaes Tulp
Rembrandt van Rijn, 1632



From MDD/IVDD to MDR/IVDR

Harmonize Standards

Horizontal Standards:

- EN 1041:2008 on information supplied by manufacturer → likely to remain harmonized
- EN ISO 15223-1:2016 on symbols → likely to remain harmonized
- EN ISO 17664:2004 on resterilization → probably harmonized
- EN 15986:2011 on labelling of devices containing phthalates → could be harmonized
- Device specific standards may not be harmonized (e.g. EN ISO 14408:2009 on marking and accompanying information for tracheal tubes designed for laser surgery)

User Information Under the MDR/IVDR

- Identification of the device and the manufacturer
- Relevant safety and performance information
- Marketing information may not be relevant under the MDR

Location Of Information Under the MDR/IVDR

- On the device, or
- On the label, or
- On the package, or
- In the Instructions for Use ('IFU'), and
- On the website of the manufacturer (if available), and:
- For medical devices also according to the Electronic labelling Directive (EU) 207/2012

Attention: Summary Of Safety And Performance

- Required for implantable devices and Class III devices (this includes dental implants…)
- '…shall be written in a way that is clear to the intended user and… the patient… and shall be made available to the public via Eudamed.' → any language of Member State where the device is distributed

Essential Information On The Device Or Label

- Identification of ‘contents of package’ (*what, how many/much, in what state etc.*)
- Crucial safety warnings
- Essential instructions

What Information Goes Where Under The MDR IVDR

- Identify all information
- Prioritize this information
- Organize how this information is brought to the user/patient
- Don’t forget to add all information, in all languages and with all older versions to your website

Language issues

Tower of Babel
Pieter Breugel The Elder, 1563

24 Official Languages In Europe

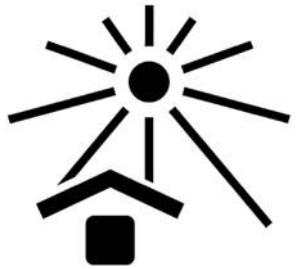
- They are all equal
- In general Member States require user information to be provided in their national language(s)
- Combination products: the 'device part' must comply with Annex I (GSPR)
- No distinction between risk classes
- There are few exceptions

In general: The Label should be in the language(s) of the Member State where the device is distributed

Language-sensitive Information

- If the understanding of a message depends on understanding specific words, this is language-sensitive information
- Examples:
  - ‘Electrical Children’s Wheelchair’
  - ‘Do not touch the surfaces marked with X’
  - ‘Cut to size’

Non Language-sensitive Information

- Some information can be understood regardless the language of the reader
- Examples:
  - XT-22
  - 

Possible Language-sensitive Information

- Some information may or may not require a real understanding of the words to be understood.
- Examples:
  - Device name: ‘Wheelie Bob’
  -

What Sort Of Label Do You Prefer?

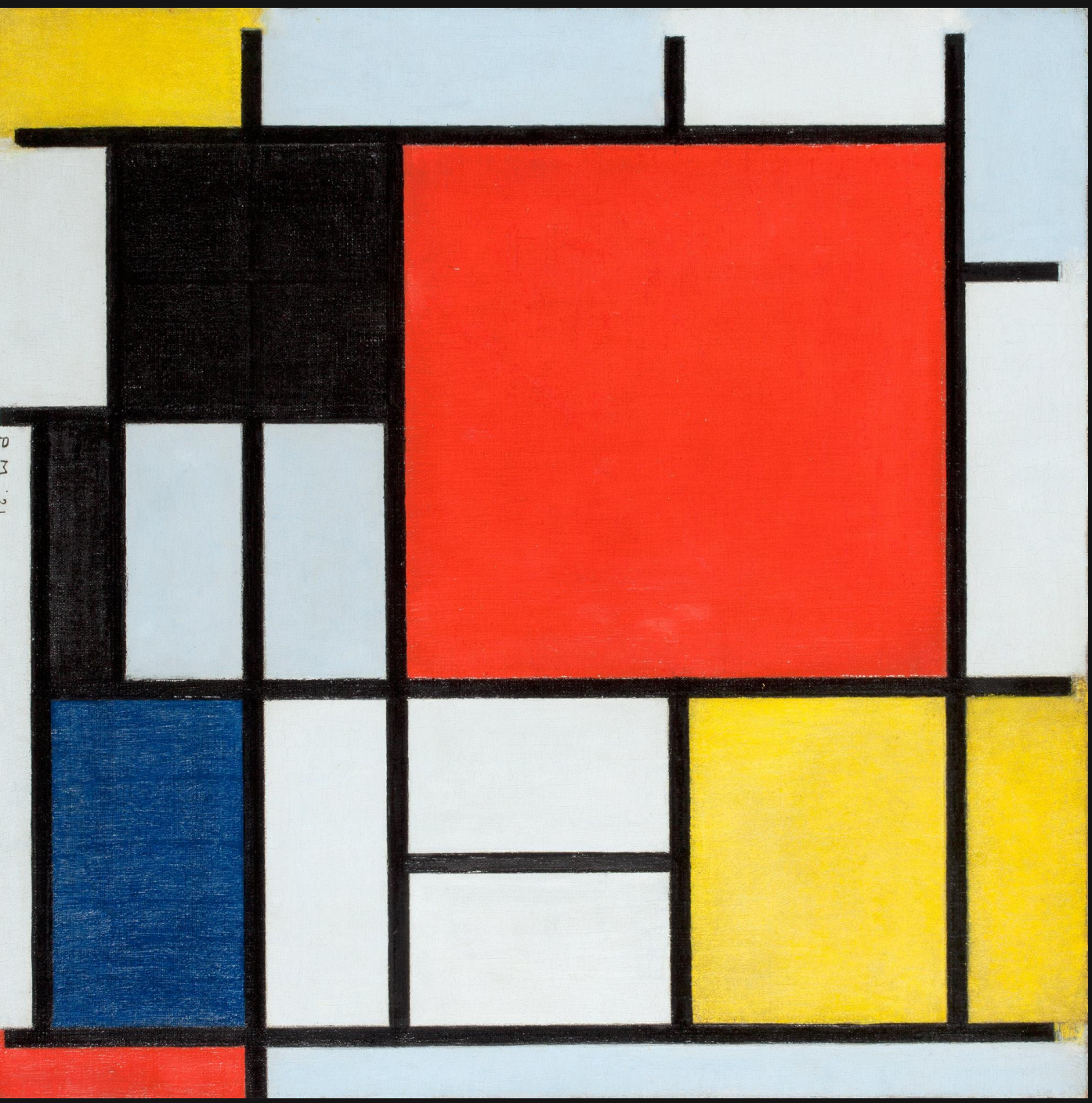
- Covering ‘The World’
- Covering Europe
- Covering specific (groups of) Member States

Language Issues In Europe

- English alone is not acceptable for Europe
- Analyze the level of language sensitivity of the information on your labels
- Determine the necessity of that information on your label
- Use symbols to reduce the level language sensitivity

Label design considerations

Piet Mondriaan
Tableau, 1921



Information On The Label

‘Technical’ information:

- Device identification
- Manufacture identification
- Some warnings
- UDI (device identification and production identification)
- Etc.

‘Clinical’ information:

- Intended use
- (Contra)indications
- Other warnings
- Etc.

Label Quality

- Correct
- Adequate
- Up to date
- Consistent
- But most important: clear to the intended reader

  - → *likely it will also be in compliance*

Intended Readers

- Patients
- Care givers
- Physicians
- Competent authorities
- Competitors
- others

European Database For Medical Devices: Eudamed

- Database for Economic operators, devices and UDI, certificates, clinical studies, vigilance and market surveillance
- Part will be publicly accessible
- Make sure data on the label/IFU is consistent with data in Eudamed

Example 1: ‘European’ Label

- No language-specific information
  - This includes the device identification and quantity in package
- Use symbols
  - Where necessary explain symbols in IFU
- This may impact the design of your device

Example 2: ‘Member State Specific’ Label

- Create a need for detailed identification of your devices
- Create a need for detailed instructions to be provided on the label
- Create a need for detailed warnings
- Attention: each language must have its own UDI-DI

Translating Into National Languages

- The manufacturer remains responsible for the translation
- Translation should be within the scope of the quality management system
- If a local distributor adds his own label or IFU he takes up the role of the manufacturer
- ‘Rogue’ translations may also breach trademark rules

Design Of User Information

- Analyze data
- Understand risks and opportunities
- Design user information on all levels simultaneously
- Adapt to changes as soon as reasonably possible

Thank you

Official Cheese Weigh Locality
Unknown artist

UNITED LANGUAGE GROUP

For MDR consulting services, contact Ronald Boumans

Phone: +31 70 345 8570
Email: Ronald.boumans@UL.com

For more information about United Language Group's services, contact Jackie Weber

Phone: +1 612.400.6509 (GMT-6)
Email: jacqueline.weber@ulgroup.com

To reach United Language Group in the European Union, contact:

Angela Caballer
Email: Angela.Caballer@ulgroup.com
Phone: +34 697 763 431

Eileen Kerry
Email: Eileen.Kerry@ulgroup.com
Phone: +353-91-393054