MedTech Europe Workshop
The impact of the IVD Regulation on labelling

10 – 11 July 2019

Thon Hotel EU, rue de la Loi 75, 1040 Brussels, Belgium

This is a 1.5 days' workshop, which ends with a light lunch on 11 July

THIS WORKSHOP IS FREE OF CHARGE* AND OPEN TO:

- MedTech Europe Corporate Members
- Corporate Members of National Associations affiliated to MedTech Europe

Please distribute this invitation within your company or among your members.
MedTech Europe reserves the right to limit the number of participants on a first-come, first-served basis.

Please register by 12 June 2019 using this link: https://www.eventbrite.com/e/the-impact-of-the-ivd-regulation-on-labelling-registration-61097195356. *A fee will be charged to late cancellations and no-shows.

You may find a **discounted rate offered by the Thon Hotel EU** to participants under this link: https://www.thonhotels.com/event/medtech-europe/ (NB: rates only available until 21 June!)

About the workshop
There are a many new requirements for what information to place on the device label and in the instructions for use under Regulation 2017/746/EU when compared with Directive 98/79/EC. In many cases the IVD Regulation makes requirements explicit that are already common practice and or found in the IVD labelling standard series ISO 18113. MedTech Europe has developed guidance on how to implement changes to labelling requirements. This workshop aims to give an overview of the new requirements and dive into more depth on specific topics:

- Intended purpose on the label and in the instructions for use
- 'Single use' devices
- Safe disposal information requirements
- Labelling for self-tests, near-patient tests and software
- Batch-to-batch information requirements

Participants will discuss these and other labelling questions in both break-out and plenary sessions. This will both act as a way to check/review the industry consensus and support participants in preparing to implement their own labelling changes.

MedTech Europe
from diagnosis to cure

MedTech Europe Workshop
The impact of the IVD Regulation on labelling

10 – 11 July 2019
The workshop ends with a light lunch on 11 July

Thon Hotel EU, rue de la Loi 75, 1040 Brussels, Belgium

draft Agenda

Wednesday 10 July

9.30 – 10.00: **Registration and Coffee**

10.00 – 10.15: **Welcome and Introduction**
Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*

10.15 – 10.30: **Implementation of the IVD Regulation**
Petra Zoellner – *MTE Senior Manager Regulations & Industrial Policy*

10.30 – 11.15: **Labelling – presentation of guidance, overview of key changes**
Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*
Petra Zoellner – *MTE Senior Manager Regulations & Industrial Policy*

11.15 - 12.30: **Break-out session I – Intended purpose**

- Updated requirements for intended purpose
- Requirement to label if device is for single use only

Questions including:

- *What is meant by the 'intended purpose'?*
- *What is the requirement for the label? How does this differ from the requirement in the instructions for use?*
- *Legacy: How should intended purpose be addressed for products already on the market?*
- *What is meant by 'single use' devices?*

12.30 – 13.30: **Lunch**

13.30 – 14.15: **Plenary discussion** – feedback from Break-out session I
Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*

14.15 - 15.30: **Break-out session II – Safe Disposal** (infection, environmental and physical)

- Labelling for hazardous substances
- New disposal requirements

Questions including:

- *What are the new requirements?*
- *How should the device be labelled for hazardous substances? What can go in the instructions for use? What about safety data sheets?*
- *How to address the new requirements re: information on disposal of the device and related substances?*

15.30 – 15.45: **Break**

15.45 – 17.00: **Break-out session III – Self-tests, near-patient tests and software**

- New requirements for self-tests and near-patient tests
- Interpretation of labelling requirements for software

Questions including:

- *What symbols should be used and where?*
- *How would you label a near-patient test versus a self-test?*
- *How would you label a software product?*

17.00 – 17.45: **Plenary discussion – feedback from Break-out sessions II and III**

17.45 – 18.00: **Conclusions from Day 1 and wrap-up**
Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*

19.00: **Optional dinner** for interested attendees (paid dinner – details to follow)

Thursday 11 July

9.00 – 9.30: **Rooms and coffee available**

9.30 – 9.45: **Welcome back**

Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*

9.45 - 11.00: **Break-out session III – Batch-to-batch variation**

- New requirements to provide information on batch-to-batch variation

Questions including:

- *What is maximum (self-allowed) batch-to-batch variation (calibrators & control materials)? How to inform the user (20.4.1 (u))?*
- *What is meant by "….information regarding batch to batch variation provided with relevant figures & units of measure" (20.4.1 (v))?*
- *When should the user be informed about batch-to-batch variation? How to inform the user?*

11.00 – 11.45: **Plenary discussion – feedback from Break-out session IV**

11.45 – 12.00: **Workshop conclusions and wrap-up**

Richard Saunders – *Chair, MTE Labelling (IVD) WG (Ortho Clinical Diagnostics)*

12.00 – 13.00: **Light lunch**

13.00 End of the Workshop