Guidance on Material Declaration in the *in vitro* diagnostic medical device and medical device industry

31 January 2019

[Version 1.0]

This guidance is intended to ensure common understanding in the field of material declaration. Material declaration is used to transfer information on the chemical composition of products, and related regulatory information, within the supply chain to allow the corresponding downstream user to comply with constantly evolving global regulatory requirements and appropriately deal with shifting stakeholder expectations.

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1. Aim and scope

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. This document relates to compliance and stakeholder communication in the field of chemical, environmental and product legislation. It is meant to provide:

- High-level background on what a material declaration is;
- A rationale as to why **full** material declaration (FMD) will be beneficial to customers, manufacturers, and suppliers;
- Guidance for medical technology manufacturers to communicate a common message up the supply chain on the background and importance of providing full material declarations;
- A common understanding to set the basis for a future standardisation in the field of material declaration.

The present document includes the full geographic scope and all products purchased and marketed by the *in vitro* diagnostic (IVD) medical device and medical device industry.

2. Introduction

Companies are confronted with an ever-growing challenge to declare compliance with a great variety of regulatory requirements, to document and report chemical composition, to track the volumes of substances, and to document the origin of product components etc.

Since the entry into force of new regulations such as REACH[1], the Medical Device Regulation (MDR)[2], the California Proposition 65 List[3] and the inclusion of IVDs and medical devices into the scope of the RoHS Directive[4], the demand for information on material compositions for the purpose of compliance has increased rapidly to an extent that the regulatory requirements and the related requests are increasingly difficult to be handled in the previous ad-hoc manner.

Customers - private and public - are enquiring more and more about the composition and origin of medical technology products, not just for regulatory purposes, but also to be responsive to various individual, communal, or societal expectations. Many customers are implementing voluntary green procurement, environmentally conscious design and sustainability programmes, or may have other non-regulatory requirements to meet.

More and more companies are also devising and launching their own material declaration schemes to meet the related regulatory and marketing challenges and thus strengthen their competitive position.

Compliance with material-related legal obligations is essential for obtaining access to the pertinent markets. The seamless transfer of material declarations in the supply chain is thus in the common interest of all companies involved. An important question for companies in the supply chain is how this transfer of material declarations can be designed in the most reliable and cost-efficient way while protecting confidential business information.

The above-mentioned challenges lead to an increasing need of digitisation of compliance and stakeholder communication in the field of chemical, environmental and product legislation. The evolution of material declaration tools is one major element to support this development.

3. Definitions

Material declaration

A report related to a product (substance, mixture, or article of various complexity) in the supply chain on at least one of the following data elements:

- Compliance with specific material-related legislation;

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
[3] Safe Drinking Water and Toxic Enforcement Act of 1986
[4] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- The presence or absence of specific substances;
- The presence or absence of certain material properties;
- Chemical composition (per product and/or component);
- The origin of materials, that is, for instance, from which species, manufacturing process (or recycling), region, country, or company the material originates;
- Compliance with specific customer specific material related requirements, such as social aspects and/or excluding certain sources or harvesting/manufacturing methods.

Such information is important for responding to regulatory and/or customer requirements.

Table 1. Examples of declarations with different levels of detail

Compliance Declaration (CD)	Identifies substances above or below a threshold including applicable exemptions.
Full Material Declaration (FMD)	100% (w/w) of all substances ("recipe") present in the product.
FMD+	FMD plus additional information, e.g. process chemicals, social aspects, biologic or geographic origin, kosher, halal etc.

Note: The description of different types of declarations are just to point out that the level of detail can vary. Various intermediate forms or combinations exist in practice.

Material declaration tools

Technology that allows communication and management of supplier information to:

- Store and to manage data on the chemical composition, the origin, and the weight of any product in the supply chain;
- Document compliance of suppliers with regulatory requirements;
- Monitor and document compliance of internal processes;
- Request supplier declarations and handle material declarations;
- Generate statements of compliance;
- Generate compliance statements or material declarations for customers and authorities.

4. Industry best practices for material declaration

Downstream users/customers – requesters of information

- Minimise the number of inquiries;
- Avoid irrelevant inquiries;
- Provide training related to data requests;
- Have resources available to support technical questions;
- Have policies and safeguards in place to ensure appropriate handling of confidential business information;
- Provide contact details (including at least an e-mail address and potentially a direct telephone number) for questions.

Upstream suppliers - providers of information

- Identify and provide a functional (not person related) e-mail address for inquiries including a telephone number for direct contact (if available, a webpage address can be provided as well);
- Cascade the expectations for information required for FMD to their supply chain;
- Provide full material declarations at product level;
- Update FMD's for all material changes;
- Respond within an agreed upon timeline.

5. How to deal with concerns on IP?

In most cases, full substance declaration by itself will not result in a concern for loss of intellectually property (IP). However, in some instances, disclosing the full material makeup of a component, could convey key intellectual property information (for example, a homogenous part made from a highly proprietary resin).

Agreements can be made between the supplier and their customer that can result in achieving FMD while still protecting any key intellectual property, such as by allowing FMD's to remain confidential to the originator while still allowing for the downstream benefits (by systemically comparing the FMD to all applicable regulations), without disclosing the FMD information downstream. Tools may also allow for a small percentage of the FMD to remain "non-disclosed", as long as the supplier makes certain assurances about those non-disclosed substances.

Any company's intellectual property is critical to that company's continued success. Maintaining valuable intellectual property and supporting FMD have been shown not to be mutually exclusive.

6. Summary of benefits of FMD

Promulgating FMD information down the supply chain will result in tremendous benefits to all stakeholders.

Changing regulations and customer requirements lead to frequent recurring assessments of substance content in products. The list of regulated substances to declare against for IVDs and medical devices continues to grow significantly.

As the number of regulated substances grows, the time and effort required to assess and declare against all the regulated substances will start to become more and more unmanageable. For many products, performing chemical analysis to identify substance content is not feasible.

The information required from an FMD is best obtained by requesting information up the supply chain, and the necessary number of tiers up that chain may not be as large as expected, even for complex components (such as printed circuit board assemblies).

Some of the many benefits of FMD include:

- It provides a format for cooperation between upstream suppliers and downstream users to achieve a comprehensive material declaration while respecting each party's valuable intellectual property, time and resources. In instances where FMD information could result in disclosing intellectual property, there are systems and methods available to maintain confidentiality where that is deemed to be business-critical.
- An FMD allows for an automated assessment (using the proper processes) against all current and new compliance requirements, which significantly minimises effort up and down the supply chain.
- When regulations are updated, systems can automatically check regulated substance presence to support compliance, minimising additional time or effort throughout the supply chain.
- For upstream suppliers, FMD may have the following specific benefits: Having an FMD available for all product lines will allow to readily provide information to customers across all industries, not just the medical technology industry.
- An FMD is a valuable reference to determine if developing regulations may impact the use of substances and materials in a product to determine redesign or raising awareness to regulatory stakeholders for the continued and necessary use of impacted substances and materials.

7. The FMD journey

Industry-wide acceptance of FMD may not happen overnight, but only by continuing to take proactive steps now will it be possible to achieve this critical goal in the near future.

An interim solution for communicating compliance with all of the global environmental substance regulations is providing Compliance Declarations. However, this approach still requires frequent requests and updates throughout the supply chain as regulations change.[5]

There is other information beyond FMD that may also be of interest (see Table 1), however determining how to best obtain this type of information should not detract from pursuing the primary FMD objective.

MedTech Europe members will be increasing their engagement with their supply chain to work together to achieve FMD, and to realise mutual associated benefits. The anticipated benefits include resource cost savings, improved efficiencies, more detailed product information, and improved outcomes for patients and the environment.

Taking immediate steps now is vital to be able to manage current and future global substance restriction regulations, and to achieve all the benefits of FMD.

[5] If 'Full' Material Declarations reveal less than 100% of the substances intentionally added to a product, these declarations will need to be combined with Compliance Declarations for the missing part and these CDs will need to be updated each time a new requirement applies. Alternatively, the supplier may provide an updated FMD disclosing the previously undisclosed substances.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.