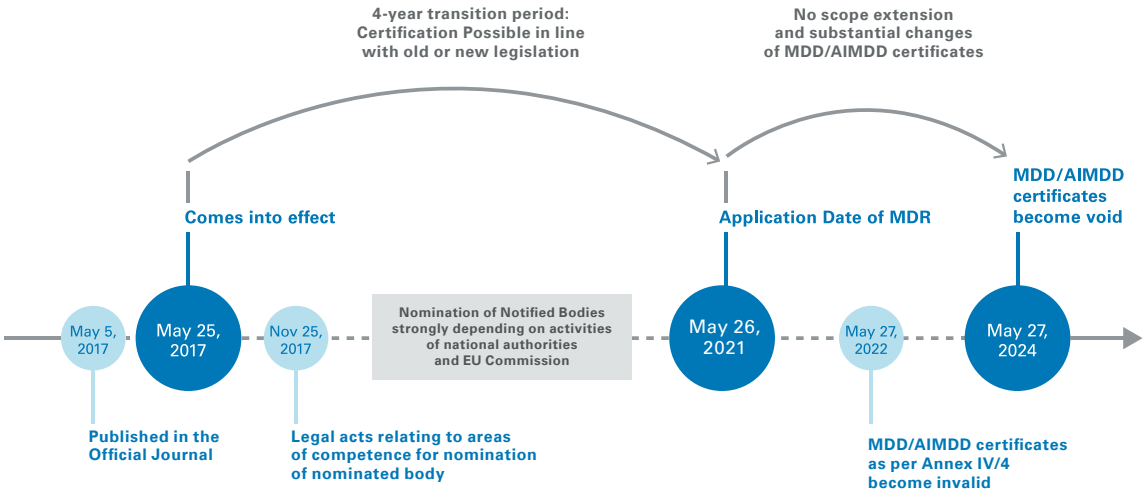
EU MDR and the Impact on Chemical Substances in Medical Products

Background

In April 2017, the European Union (EU) adopted the new Medical Device Regulation (MDR), (EU) 2017/745 EU MDR. This new regulation is replacing the two existing directives – the Medical Device Directive 93/42/EEC (MDD) and the Active Implantable Medical Device Directive 90/385/EEC (AIMDD). After a three-year transition period, the new Medical Device Regulation will enter into effect on May 26, 2021.

TRANSITIONAL PROVISIONS



The Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices was published on 24 April 2020 in the Official Journal of the European Parliament!

The main objective to the amendment was to postpone the date of application from 26 May 2020 to 26 May 2021. Along with this postponement other dates of applications of other provisions were adopted as well. Please find the official publication of the Amendment Regulation here.

What manufacturers should understand is that this new regulation is a prerequisite for access to European markets and will significantly change the market access structure for the EU. As a result, manufacturers need to start preparing now to ensure product compliance to the new MDR by the application date. This paper will highlight the impact the new MDR will have on chemical substances used to manufacture medical products, proposed solutions, and long-term considerations to ensure compliance in the future.

Key Changes to Chemical Substances in Medical Products

Annex 1, Chapter II, Section 10.4.1 of the new EU MDR explains the need for a risk assessment to identify if any of the CMR 1A and 1B substances, listed in the Regulation (EC) No. 1272/2008 - Classification, Labelling and Packaging (CLP), are in your materials that are considered "invasive." This means that devices shall be designed and manufactured in a way that aims to reduce the possible risks posed by substances or particles such as wear debris, degradation products, and processing residues that may be released from the device. In greater detail, devices, or those parts thereof or those materials used therein that:

- are invasive and come into direct contact with the human body,
- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

(a) substances which are carcinogenic, mutagenic or toxic to reproduction (‚CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council1, or

(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council2 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No. 528/2012 of the European Parliament and the Council3, in accordance with the criteria that are relevant to human health amongst the criteria established therein.

Part 3 of Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council is the "Classification, Labelling and Packaging" (CLP) of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006.

Proposed Solution – Risk Assessment

The Restriction of Hazardous Substances (RoHS) and Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations should have taught us all about assessing the risks of hazardous substances in materials. While adding more substances to the list is cumbersome, it is no different than what the medical device industry has been doing for years. The difference here is defining those materials that are considered invasive, as opposed to the final completed product.

It usually starts with the R&D department requiring a specific material for a specific application. The application could require a number of different aspects such as a smooth surface, flexibility, non-permeable, ability to be sterilized, specific color, etc. Regardless of the different requirements, the material has to be chosen, the specifications and material data sheets have to be approved, and any chemical substances being controlled are either tested or declared below the thresholds of any legislation: RoHS, REACH, California Proposition 65, Bio-Compatibility, etc.

A critical part of the process is also choosing, qualifying and auditing a vendor. There are both high-risk and low-risk suppliers, based on your supplier risk assessment. Once an approved vendor is chosen, they are then given extrusion or mold measurements and the material is formed into a part for use in manufacturing a product. Finally, a quality inspection approves its final form and fit, and then the part is incorporated into a medical device.

Hypothetically, the risk here cannot be overlooked: The release agent used on molding or when extruding the material into a part was never considered, nor approved for use. Residual amounts of the release agent remain in the product and upon testing the material for final approval, the product fails.

Medical devices typically go through bio-compatibility testing as well to ensure its safe use with patients. The new requirements under the EU MDR look at those materials considered "invasive." The current risk assessment in place for hazardous substances must now be expanded to include this new list of CMR 1A and 1B substances, including endocrine-disrupting properties (EDPs) in accordance with the procedure set out in Article 59 of Regulation (EC) No. 1907/2006 (REACH).

TÜV Rheinland can assist companies in developing their risk assessments for hazardous chemicals in materials. Each product is unique and therefore risk assessments can be challenging. TÜV Rheinland's Technical Competency Centers (TCC) around the globe provide a professional view into regulations that restrict or ban chemicals in materials.

Future Direction / Long-term Focus

Knowing the exact percentage of each chemical substance in all of your materials would be the perfect scenario for an Original Equipment Manufacturer (OEM), yet that is not always possible. There will always be a balance of collecting data (declarations, certificates of conformity, full data disclosure) and actual chemical testing to provide a complete, full-rounded risk assessment for a product or material.

Documentation on what a company has done to prove compliance will be audited regularly by Notified Bodies. This will be the company's Technical Construction File (TCF). It is important to understand that collecting data only from suppliers will not be enough to satisfy these requirements. As with RoHS and REACH, testing of high-risk materials and high-risk suppliers is recommended. Discovering which supplier and which material is considered a high-risk is the process outlined by your organization's internal procedures. A Supplier or Vendor Qualification Program is used to qualify a vendor for your organization, whereas a Material Qualification Process is used to qualify materials making up your end product. The outcome of these programs should generate a high/low-risk assessment which will act as a guidance document on how to proceed with your due-diligence efforts.

Some examples of high-risk for vendors could be their geographical location, their ability to provide requested documentation, whether the data provided is current or relevant, and if their internal quality process is regularly audited or not. An example of a high-risk material could be a flexible polymer. Polymers, PVC, adhesives, inks and paint can contain phthalates. Phthalates are now controlled under the CPSIA (children's products), CalProp 65 (any product), RoHS (electrical and electronic equipment), REACH (any product), and others.

Conclusion

The list of substances of concern under the new EU MDR points directly to Part 3 of Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council. This is the CLP list known as the "10th Edition" of "Classification, Labelling and Packaging" (CLP) of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006.

This list contains the CMR 1A and 1B substances and can be filtered to only include those substances. Furthermore, the list can be cross-referenced with the REACH regulation to avoid assessing the same substance twice. Afterwards, you will have a condensed list of targeted substances to begin with.

This is where the work begins, as not all substances in that list would be found in common materials such as textiles, plastics and alloys. Assessing which substances could be found in your materials will be a combination of the company's knowledge to intentionally add substances to materials, control through declarations and certificates, and actual chemical testing of the final material.

Since products are not always designed to be sold in the same region they are manufactured, other testing may be required. Testing for RoHS, REACH SVHCs, POP Regulation, California Proposition 65, Packaging requirements, Canada Health, and others, will ensure your product can meet various global market requirements. Testing for these different regulations simultaneously can be beneficial and will reduce the overall cost as there are similar methods used in the regulations.

When all the work has been completed, you will have a TCF laying out the steps that have been taken to identify hazardous substances in your products. For EU MDR, if any of those substances has exceeded 0.1% by weight of the material, labelling will be required as per (EU) 2017/745, Annex 1, Chapter II, Section 10.4.5. "Labelling."

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