VDMA Arbeitsgemeinschaft Medizintechnik

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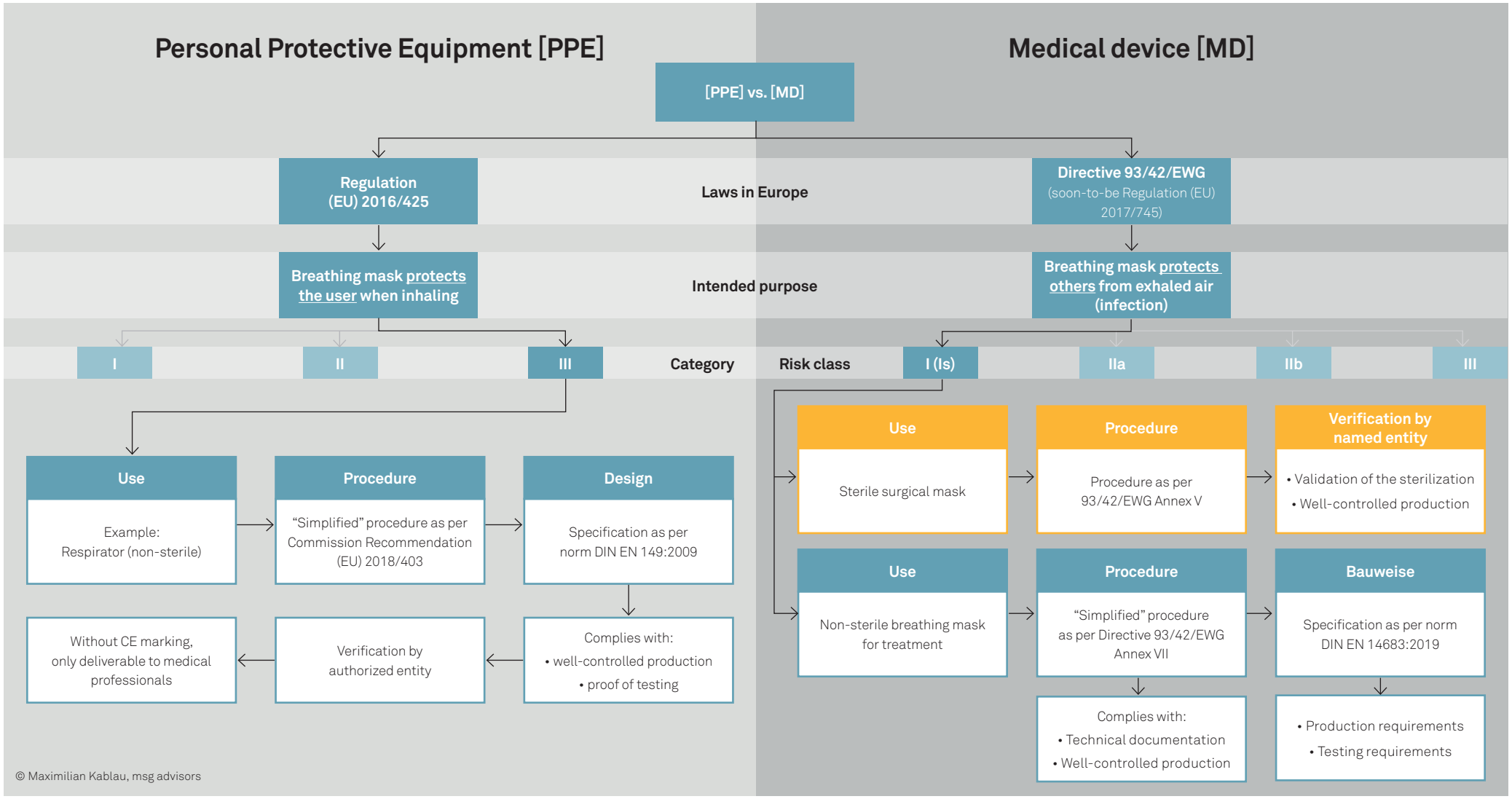
GUIDELINES PPE / MD



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The Corona pandemic is posing previously unseen challenges for our society – in our personal lives, as well as in politics, business and science. We can only slow the spread of the pandemic by working together. The highest priority at the moment is to ensure the deliverability of protective equipment. For that reason, the following guide was published in collaboration with the European Commission, the German Federal Ministry of Health and health organizations to help companies quickly convert their production to the production of breathing masks. The goal is to increase supply, especially with breathing masks being used as personal protective equipment (PPE) and as medical devices.

In its Letter of Recommendation of 03/31/2020, the Federal Institute for Drugs and Medical Devices (BfArM) defined three categories of masks: 1. "Community Masks", i.e. homemade cloth masks; 2. Surgical Masks; and 3. Particle-Filtering Half Masks. Community masks do not have to meet any regulatory requirements or standards and are thus not described in any further detail in the guide.

For all masks in either category 2 or 3, the manufacturer must define the intended purpose. Based on that definition, the masks are then classified as either surgical or PPE. If the mask protects the wearer from infection, then it is considered PPE. If the mask protects patients/third parties from infection by the wearer, then it is considered a surgical mask. Different scopes with different regulations exist for both product groups (see diagram on Page 1 for details).

Regulation (EU) 2016/425 provides the legislation that governs PPE. The text was temporarily amended, and in some cases replaced, on 03/13/2020 with Recommendation (EU) 2020/403. PPE masks can now be introduced to the market without the CE mark; however, any such masks can only be provided to medical professionals. A recommended design for PPE masks was proposed in norm DIN EN 149:2009. To give companies the opportunity to quickly start production, the specifications defined in the norm must be met. Companies must prove that the PPE masks are suitable for the designated purpose through product tests and well-controlled production. The evidence provided is then verified and approved by an authorized entity.

Medical devices are covered by Directive 93/42/EWG. In this case, a differentiation is made between sterile and non-sterile products. Details on non-sterile breathing masks are provided in DIN EN 14683:2019. The legal requirements can be found in Annex VII of Directive 93/42/EWG. Basically, companies must have technical documentation to accompany their product and well-controlled production. Sterile products must include proof of a valid sterilization process; the process itself is verified by a named entity. The requirements for non-sterile masks also apply. Further details can be found in Annex V of Directive 93/42/EWG.

We would be happy to help you implement the guidelines. Please feel free to contact us at the following:

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