AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP Statement on the MDR date of application

Today, the Regulation (EU) 2017/745 on medical devices, more commonly known as MDR, becomes applicable. The Association of the European Self-Care Industry (AESGP), representing manufacturers of self-care medical devices, welcomes the implementation of the new legal framework applicable to medical devices. It will ensure continued access to safe devices for patients, consumers, healthcare professionals and healthcare systems in Europe and abroad. AESGP would like to acknowledge the time and effort put by the regulators in the implementation process as well as the continued cooperation with EU decision-makers and other stakeholders.

While the date of application represents a very important step, **it does not represent the end of the MDR implementation process.** AESGP and its members have been putting significant resources to be compliant with the new obligations and responsibilities and will continue to do so in the coming years to support a successful transition to the MDR.

Aiming at an adequate legal framework for safe and effective consumer health products, it is of critical importance for AESGP members that the **recognition of substance-based medical devices by the MDR** is now properly and proportionately reflected in this implementation phase of the Regulation.

Overall, **several significant challenges remain to be overcome** before a fit for purpose MDR system delivering a real European Single Market for medical devices. Some of these include:

- **more capacities at Notified Bodies level** are needed to ensure that all MDD certified devices can transition on time
- certain **key guidance documents are still to be developed** to foster harmonized interpretation, notably on classification rules as well as on borderline and demarcation with medicines,
- the **EUDAMED database** is to be finalised and made fully functional - until then all deployed modules should be uniformly used throughout all Member States.

AESGP looks forward to its continued cooperation with EU regulators and other stakeholders in this new phase of the implementation process to overcome the remaining challenges and to successfully complete the transition to the MDR.

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