Joint statement on the

Commission Delegated Regulations (EU) (C(2026) 1798 and C(2026) 1809), concerning so-called well-established technology (WET) devices

On 20 March 2026, the European Commission published two implementing regulations (C(2026) 1798[1] and C(2026) 1809[2]) to the Medical Device Regulation (EU) 2017/745 (MDR), currently under revision. The implementing regulations concern so-called well-established technology (WET) devices, for which certain exemptions from the MDR are to apply. The listed device groups are intended to include relatively simple products characterised by a common and stable design with a low level of innovation, well-known safety and clinical performance as well as a long history of market use. The listed WET medical device types falling under Class IIb are intended to be exempt, with immediate effect, from the obligation to undergo an assessment of the technical documentation pursuant to Article 52 of the MDR. The listed WET medical device types falling under Class III, on the other hand, are exempt with immediate effect, pursuant to Article 61(6), from the obligation to conduct a clinical investigation.

We, the undersigned organisations, have important concerns regarding this approach.

First of all, the WET list does not include any individual product; instead, generic product groups are listed without clarification of their characteristics. Key factors, such as the materials used, the technology employed, or the intended purpose are completely overlooked. Moreover, the product groups are not mapped to the European Medical Device Nomenclature (EMDN) established under the MDR, nor is there any reference to existing product-specific requirements that would enable a reliable interpretation and assessment of the products concerned.

This, in turn, could lead to:

1. Increased risks for patients, as high-risk products may be subject to less stringent requirements.
2. Inconsistent interpretations by manufacturers, notified bodies (NBs) and authorities, contradicting the European Commission's original objective. It is left to the interpretation of manufacturers and NBs to determine whether an individual product qualifies as a WET.
3. Disputes between NBs and manufacturers as to whether a product constitutes a WET, potentially resulting in delays in market access.

Furthermore, the lists include product groups within which certain individual products have previously been subject to market surveillance actions and withdrawn from the market due to safety concerns. For example,

[1] COMMISSION DELEGATED REGULATION (EU) …/... amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of implantable devices and class III devices exempted from the obligation to perform clinical investigations

[2] COMMISSION DELEGATED REGULATION (EU) …/... amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the list of class IIb implantable devices exempted from the obligation to perform an assessment of the technical documentation for every device

atrioseptostomy catheters for cardiac surgical procedures in newborns were withdrawn from the market by two manufacturers following serious incidents, some of them fatal. In our view, such products must not be regarded as WET devices.

Bone substitute materials, on the other hand, should also not be listed for the additional reason that they represent a highly heterogeneous product group. They may, for example, be of mineral origin or contain synthetic components. Their use may be envisaged in dentistry as well as in trauma or tumour surgery. They may release medicinal products or contain or consist of biological substances, for which special precautions are required to prevent undesirable contamination, for example by viruses or prions. In the first consultation procedure pursuant to Article 54 of the MDR, a bone substitute material derived from porcine teeth was assessed and classified by the competent expert panel as giving rise to a health concern.[3]

As part of the European Commission's broad stakeholder consultation, specific individual products were identified as potentially qualifying as WETs. The Delegated Regulations should therefore list those individual products rather than broad, generic groups of products.

In light of the concerns set out above, the proposed list cannot be supported in the current form and requires substantial revision to ensure legal certainty, consistent interpretation and alignment with the objectives of Regulation (EU) 2017/745.

[3] Opinion in the context of the Clinical Evaluation Consultation Procedure (CECP) - Expert panels on medical devices and in vitro diagnostic devices (Expamed).

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