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Bucharest, 17 July 2026

Mr. Victor Negrescu
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Member of the European Parliament
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Mr. Nicolae Ştefănuță
VP of the European Parliament,
Substitute, SANT Commission

Subject: Targeted revision of the Medical Devices and In Vitro Diagnostics Regulations – SANT draft report (2025/0404(COD))

Esteemed Romanian members of the European Parliament,

On behalf of the American Chamber of Commerce in Romania (AmCham Romania), through its Healthcare Committee, representing over 600 American, international and Romanian companies, including manufacturers and importers of medical technologies active on the Romanian and EU markets, we would like to share our position on the draft report of the Committee on Public Health on the targeted revision of Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR), published on 30 June 2026.

We welcome the balanced approach of the draft report, which advances the simplification objectives of the Commission proposal while preserving a high level of patient safety. Several of its provisions address long-standing, practical difficulties reported by our member companies. Ahead of the deadline for tabling amendments, we respectfully ask you to support the retention of the following provisions in the form proposed by the Rapporteur, and to oppose amendments that would weaken them:

- **Recertification and surveillance (Amendment 86)** – ensures that the validity of a certificate remains unlimited. We support the clarification that periodic reviews carried out during the validity of a certificate must not become disguised recertifications based and in amounting to a full reassessment. Instead, surveillance activities, including periodic reviews should remain proportionate and risk-, preventing unnecessary duplication.
- **Periodic safety update reports (Amendments 95 and 96)** – introduce a genuinely risk-based differentiation of reporting obligations per device risk class, strengthening patient safety relative to the Commission proposal while keeping obligations proportionate.

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- **Structured dialogue (Amendment 113)** – enables structured and interactive exchanges, including pre-submission consultations, between manufacturers and notified bodies, improving the predictability of conformity assessments.
- **Assessment efficiency and sampling (Amendments 114, 115 and 116)** – provide that evidence from previous assessments is accepted rather than merely 'leveraged', and that issues already assessed are not re-assessed, avoiding duplication without reducing rigour.
- **Change notification (Amendment 123)** – clarifies the scope of information to be provided on changes to the device range covered by a certificate and confirms that additional audits or documentary reviews are required only where necessary.
- **International regulatory reliance (Amendment 29)** – reinforces reliance on internationally recognised quality management schemes, including ISO 13485 and MDSAP, avoiding duplicative audits.
- **Importer obligations (Amendment 109)** – introduces a risk-based, proportionate approach to importer verification obligations under the IVDR. We support this amendment and respectfully suggest that the same approach be mirrored in the MDR, where it is currently absent, to ensure consistency across the two Regulations.
- **Clinical evidence and equivalence (Amendment 9)** – maintains, by deleting the recital that would have removed it, the current requirement for a contractual arrangement governing access to the technical documentation of the equivalent device, ensuring that equivalence claims – particularly for high-risk implantable devices – remain supported by robust, product-specific clinical evidence and preserving incentives for manufacturers to generate their own clinical data. Amendment 92 complements this approach by excluding class III implantable devices from reliance on equivalence, and we equally support its retention.
- **Reprocessing of single-use devices (Amendment 38)** – confirms that it remains the manufacturer's responsibility to determine whether a device is intended for single use or may be reprocessed, based on the design, construction, materials and properties of the device, rather than establishing a general presumption of reprocessability as in the Commission proposal. With regard to the reasoned justification required where devices intended exclusively for use in health institutions are designated as single-use, we ask that this requirement remain proportionate and risk-based: since reprocessability is ultimately determined by device characteristics and patient safety considerations rather than the setting of use, the justification should be able to rely on the existing technical documentation, without creating a new, stand-alone administrative layer. Beyond this amendment, we believe a broader discussion is needed on the remaining aspects of the reprocessing framework, in particular Member States' discretion over whether reprocessing is permitted in their health systems, the reprocessor's status and full accountability as manufacturer of the reprocessed device, and patient information and informed consent.

These provisions respond to concrete operational challenges – duplicative audits and assessments, unpredictable certification timelines and disproportionate administrative requirements – that affect the

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availability of medical devices for Romanian and European patients and the competitiveness of companies operating in the EU.

We remain at your disposal to provide further technical input or examples from our member companies' experience, and we thank you for your consideration.

Yours sincerely,

Georgiana Coșoveanu
President, Healthcare Committee
AmCham Romania