Statement from Philips NV:

Philips continues its efforts to strengthen patient safety and quality across the company working a multi-year program to systemically enhance our quality system, address historical issues and transform our patient safety culture. We are making progress and continue to collaborate with global regulatory agencies.

In early 2025, the U.S. Food and Drug Administration (FDA) conducted intensive inspections of nine global facilities. Six of these inspections led to no observations. Three of these inspections led to observations relating to documentation, processes and procedures. These relate to Philips Ultrasound facilities in the U.S., and a Philips site in the Netherlands which manufactures two products for the Enterprise Informatics business.

Philips has worked hard to address these observations through our quality program and continues to do so. Following these observations, in September 2025 the FDA issued a Warning Letter, which in addition to accepting various inspection observation responses from Philips and requesting further information regarding related matters, cited a number of quality system issues requiring response and/or correction by Philips. These include complaint handling, corrective and preventive action processes, control and distribution of finished devices, among other areas.

While the Warning Letter makes reference to a number of Philips products, in relation to process issues, the products continue to be manufactured and sold.

Philips takes this Warning Letter very seriously and has submitted a response to the agency in accordance with regulatory requirements.

As the FDA notes, we have already taken action to address earlier observations. We are determined to resolve these issues to the full satisfaction of the FDA with the needs of patients and clinicians central to our focus and we are committed to continuously improving our documentation, processes and procedures in close collaboration with all global regulators. Philips does not expect any material commercial impact.

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