PHILIPS

Press Information

November 14, 2021

Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification*

Amsterdam, the Netherlands – On June 14, 2021, Royal Philips' (NYSE: PHG, AEX: PHIA) subsidiary, Philips Respironics, initiated a voluntary recall notification* for certain sleep and respiratory care products to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in these devices. Following the substantial ramp-up of its production, service, and repair capacity, the repair and replacement program in the US and several other markets is under way.

As expected, the US Food and Drug Administration (FDA) recently conducted an inspection of a Philips Respironics manufacturing facility in connection with the recall. On November 12, 2021, the FDA published a list of the observations it provided to Philips Respironics. In accordance with normal practice, Philips Respironics will submit its response to the inspectional findings for review by the FDA. Importantly, an FDA investigator's list of inspection observations does not constitute a final FDA determination of whether any condition is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations. Additionally, the FDA has not changed its recommendation to patients and healthcare providers in relation to affected devices.

"In connection with the voluntary recall notification in June of this year, the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US," said Frans van Houten, CEO of Royal Philips. "We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing. Until we have concluded these discussions, we are not able to publicly provide further details on these responses. We remain fully committed to supporting the community of patients who rely on the affected devices, and the physicians and customers who are dedicated to meeting patient needs."

Since June 2021, Philips Respironics and certified testing laboratories are conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope potential patient health risks, with support from appropriately qualified third-party experts. Philips Respironics plans to make more data available to the relevant competent authorities

as soon as possible after completing the assessment of the above mentioned research and tests, which is anticipated to take place in the fourth quarter.

Separately, Philips Respironics has conducted testing to support the new silicone replacement foam. Silicone foam testing provided by Philips Respironics to the FDA on devices authorized for marketing in the US had demonstrated acceptable results. Philips Respironics continues to coordinate with the FDA and other competent authorities on its testing.

An FAQ is available here.

* Voluntary recall notification in the US/field safety notice outside the US

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About Royal Philips
Royal Philips (NYSE: PHG, AEX: PHIA) is a leading health technology company focused on improving people's health and well-being, and enabling better outcomes across the health continuum – from healthy living and prevention, to diagnosis, treatment and home care. Philips leverages advanced technology and deep clinical and consumer insights to deliver integrated solutions. Headquartered in the Netherlands, the company is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care. Philips generated 2020 sales of EUR 17.3 billion and employs approximately 78,000 employees with sales and services in more than 100 countries. News about Philips can be found at www.philips.com/newscenter.

Forward-looking statements
This statement contains certain forward-looking statements with respect to the financial condition, results of operations and business of Philips and certain of the plans and objectives of Philips with respect to these items. Examples of forward-looking statements include statements made about the strategy, estimates of sales growth, future EBITA, future developments in Philips' organic business and the completion of acquisitions and divestments. By their nature, these statements involve risk and uncertainty because they relate to future events and circumstances and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these statements.

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation.