PHILIPS

Press Information

December 23, 2021

Philips provides update on the test and research program in connection with the 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 potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in these devices. Since then, together with certified testing laboratories and other qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope potential patient health risks related to possible emission of particulates from degraded foam and certain volatile organic compounds (VOCs). Philips Respironics is now providing an update on part of this test and research program. Specifically, this update covers **the test results and assessment to date of the VOC emissions of the first-generation DreamStation devices**. The first-generation DreamStation devices represent the majority of the registered affected devices. Additional testing is ongoing.**

Review of this assessment by an outside medical panel and Philips Respironics has determined that **exposure to the level of VOCs identified to date for the first-generation DreamStation devices is not typically anticipated to result in long-term health consequences for patients**.

The update on these findings is intended to inform healthcare providers of the most recent data, but the overall guidance for physicians and patients in the recall notification remains unchanged at this time.

At the time the recall notification was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Since then, using ISO 18562 guidance, VOC toxicological risk assessments were performed by certified testing laboratories and a qualified third-party expert based on the initial and new VOC testing performed to date. Philips Respironics has made this data available to the FDA and other competent authorities and is in the process of sharing this data with healthcare providers and patients.

It is important to note that the tested DreamStation devices were not exposed to ozone cleaning, in accordance with the instructions for use. Additionally, this new assessment is limited to the evaluation of VOCs for first-generation DreamStation devices, and does not

evaluate the risks of potential foam particulates or cover other devices affected by the recall. Further health risk assessments are ongoing.**

Comprehensive particulate testing and analyses are now expected to be completed in the second quarter of 2022, as testing protocols in compliance with the full extent of the relevant ISO standards for all affected product platforms require long lead times of multiple months. Philips Respironics will continue to provide updates on findings from these assessments.

Additional information
For more information on the recall notification,* as well as instructions for customers, patients and physicians, affected parties may contact their local Philips representative or visit www.philips.com/SRC-update. The content of this press release is intended to inform healthcare providers of the most recent data, but the overall guidance for physicians and patients in the recall notification remains unchanged at this time.

* *Voluntary recall notification in the U.S. / field safety notice outside the U.S.*
** *The ongoing test and the research program includes: Assessment of the health risks associated with VOC emission of the CPAP, BiPAP and Mechanical Ventilator devices affected by the recall notification; assessment of the health risks associated with possible degraded foam particulates for all affected devices; assessment of the health risks associated with exposure of the devices to repeated ozone cleaning.*

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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.