



Press Information

April 24, 2020

FDA lifts injunction on manufacture and distribution of Philips' defibrillators in the US

Amsterdam, the Netherlands – [Royal Philips](#) (NYSE: PHG, AEX: PHIA), a global leader in health technology, announced today that its Emergency Care and Resuscitation (ECR) business is resuming manufacturing and shipping of external defibrillators for the US, following notification from the US Food and Drug Administration (FDA) that the injunction prohibiting those activities has been lifted.

This business has been operating under a consent decree with the FDA since November 2017. Under the terms of the consent decree, Philips was required to suspend manufacture and distribution of its defibrillators from specific Philips facilities in the U.S., pending FDA certification via inspection of the facilities' compliance with Quality System Regulation. However, in order to ensure uninterrupted availability of these life-saving devices in the US, the consent decree included exemptions for specific Philips Automated External Defibrillator (AED) models to continue to be manufactured and shipped, in addition to providing necessary device servicing, accessories and consumables.

Philips continues to comply with the terms of the consent decree, which remains in effect, and includes ongoing regulatory compliance monitoring and facility inspections of the ECR business and of Philips' other patient care businesses by the FDA.

"The injunction lift is an important milestone for Philips, as we have enhanced the regulatory compliance processes in our ECR business and throughout the company," said Frans van Houten, CEO of Royal Philips. "Providing our customers with safe and reliable products and solutions remains our highest priority, and I am proud that our AEDs save lives daily, with their very high reliability record."

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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 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 2019 sales of EUR 19.5 billion and employs approximately 81,000 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 release 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.