



Philips Respironics Consent Decree

Frequently Asked Questions – as of April 10, 2024

What is a consent decree?

In general terms, a consent decree is an agreement negotiated between the government and a company to resolve a civil enforcement action as an alternative to litigation. The government then presents the agreement to a court for entry as a legally binding order.

Typically, a consent decree addressing alleged non-compliance with the Federal Food, Drug and Cosmetic Act (FDC Act), requires the company to take a series of actions, with defined milestones and deliverables, to assess and remedy certain non-conformances, which usually includes undergoing third-party audits and implementing quality systems improvements.

Generally, the consent decree also imposes restrictions on the company's ability to engage in certain FDA-regulated activities (such as device manufacturing or distribution) which are lifted once the certain obligations under the consent decree have been satisfied.

Why did the FDA and DOJ seek a consent decree from Philips Respironics?

Following Philips Respironics' voluntary recall of certain CPAP, BiPAP, and mechanical ventilator devices in June 2021, FDA's inspection of Philips Respironics' Murrysville facility in the second half of 2021, and the FDA's issuance of a Form FDA 483 with inspectional observations, the FDA and DOJ began discussions with Philips in July 2022 regarding the terms of a proposed consent decree.

Philips has agreed on the terms of a consent decree with the US Department of Justice (DOJ), representing the US Food and Drug Administration (FDA). The consent decree primarily focuses on Philips Respironics' business operations in the US. The decree provides Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

Was the consent decree triggered by patient harm from recalled products?

Following the FDA's inspection of Philips Respironics' Murrysville facility in the second half of 2021 and FDA's issuance of a Form 483 with inspectional observations, the FDA and DOJ began discussions with Philips in July 2022 regarding the terms of a proposed consent decree to resolve the observations.

Why did Philips Respironics agree to enter a consent decree?

Our aim is to serve healthcare providers and their patients with innovative sleep and respiratory products and services. The consent decree provides Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

Does this mean FDA/DOJ's allegations are true?

The consent decree is not an admission of any of the allegations in the complaint. The consent decree provides Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.



What are the main terms of the consent decree?

The main terms include:

- Philips Respironics' business operations must demonstrate continued compliance with the Current Good Manufacturing Practice requirements for medical devices, as incorporated in FDA's Quality System Regulation.
- Philips Respironics will retain independent quality system experts to supervise the compliance improvement program.
- In the US, millions of patients are currently using Philips Respironics sleep and respiratory care devices. Philips Respironics will be permitted to continue servicing these sleep and respiratory care devices that are already with healthcare providers and patients, and to sell accessories (including patient interfaces), consumables (including patient circuits), and replacement parts (including repair kits).

However, the consent decree includes an injunction limiting Philips Respironics' ability to operate commercially in the US. Such a commercial restriction is typical for consent decrees. Philips Respironics will resume selling new CPAP or BiPAP sleep therapy devices or other respiratory care devices in the US only when the relevant requirements of the consent decree are met.

- Outside the US, Philips Respironics will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables (including patient circuits), replacement parts (including repair kits) and services, subject to certain requirements. It is common for consent decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of medical devices into the US.
- Philips Respironics will continue to prioritize completing the remediation of the sleep and respiratory devices under Respironics' voluntary June 2021 [recall](#). More than 99% of the actionable registered CPAP and BiPAP sleep therapy devices have been remediated globally, while the remediation of the ventilators is ongoing in coordination with the relevant competent authorities. Philips Respironics will retain independent design and quality system experts to review various aspects of the recall remediation.

How does the consent decree impact the return to market outside the US?

It does not. Philips Respironics will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables, replacement parts and services, subject to certain requirements. It is common for consent decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of medical devices into the US.

What is the financial impact of the consent decree?

As reported on January 29, 2024, as a consequence of addressing this consent decree, which is a multi-year plan, Philips recorded a provision of EUR 363 million in Q4 2023 that relates to remediation activities, inventory write-downs and onerous contract provisions. In 2024, Philips expects around 100 basis points of costs that relate to remediation activities and disgorgement payments for Philips Respironics sales in the US.

The previously stated 2023-2025 Group financial outlook of mid-single-digit comparable sales growth, low-teens Adjusted EBITA margin, and EUR 1.4-1.6 billion free cash flow now takes the consent decree into account and remains unchanged.



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When will Philips sell sleep therapy devices in the US again?

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Can you summarize what are the key relevant requirements to lift the sales injunction and the profit disgorgement obligation?

Sales injunction and disgorgement payments to occur until Covered Respironics Facilities are in compliance with the relevant requirements and the rework, replacement, and refund activities are completed in accordance with the Recall Remediation Plan.

The key relevant requirements are:

- Methods and controls to manufacture, hold and distribute sleep and respiratory care devices are compliant with the relevant requirements.
- Retain a quality system expert to inspect the Covered Respironics Facilities: processes and methods, 483 observations, MDR governance, C&R reporting, design, CAPAs etc.
- Provide the FDA a certification from retained expert that Covered Respironics Facilities are complying.

What are Covered Respironics Facilities?

The Respironics consent decree primarily focuses on Philips Respironics' business operations in the US, including its facilities in Murrysville, New Kensington, Mount Pleasant and Pittsburgh in Pennsylvania ("Covered Respironics Facilities").

Are Patient Interfaces (Masks) subject to profit disgorgement obligation for sales in the US?

Sales of masks and other consumables and accessories in the US are allowed under a separate exemption specific to those items, which does not have a disgorgement requirement.

What is Philips doing to ensure this doesn't happen again?

Philips and Philips Respironics share the same objective as the FDA to ensure the patient safety and quality in the delivery of our products, services and solutions, and are committed to working closely with the FDA and other global regulators.

The consent decree provides Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

It aligns with our plans to enhance quality throughout Philips, and we will use these efforts to further strengthen our systems and processes to achieve greater benefits for healthcare providers and their patients.

How does the consent decree impact the PE-PUR test and research program?

It does not.





How does the consent decree impact the remediation program?

Philips Respironics will continue to prioritize completing the remediation of the sleep and respiratory devices under Respironics' voluntary June 2021 [recall](#). More than 99% of the actionable registered CPAP and BiPAP sleep therapy devices have been remediated globally, while the remediation of the ventilators is ongoing in coordination with the relevant competent authorities. Philips Respironics will retain independent design and quality system experts retained to review various aspects of the recall remediation.

Does further testing need to be carried out on the silicone foam?

Philips Respironics' devices with the new silicone sound abatement foam have been subject to extensive testing in accordance with the applicable industry testing standards and may continue to be used in accordance with the instructions for use. As part of the Consent Decree, Philips Respironics will retain an expert to review and evaluate the test plan and testing for assuring the safety of the silicone replacement foam.

Can Philips Respironics produce Sleep and Respiratory Care devices at other facilities outside the ones covered by the consent decree?

Certain Sleep and Respiratory Care devices were already produced by contract manufacturers and Philips Respironics outside the US.

