



PRESS RELEASE

DEFECTIVE SLEEP APNEA DEVICES: CONVICTION JUDGEMENT UPHELD FOR PHILIPS-RESPIRONICS

THIS WAS ESTABLISHED BY A JUDGEMENT OF THE COURT OF APPEAL OF MILAN

VICTORY FOR THE APNOICI ITALIANI ASSOCIATION APS AND ADUSBEF APS:

"SATISFIED, THE RIGHT TO HEALTH PREVAILS"

THE FIRST CLASS ACTION, IN THE HEALTHCARE SECTOR IN ITALY,

COORDINATED BY THE LAW FIRM AMBROSIO & COMMODO

A PRESS CONFERENCE IS HELD IN ROME TODAY

Rome, February 1 - The **multinational Philips SPA and Respironics Deutschland GMBH** will have to pay a **penalty of 20 thousand euros for each day's** delay -- starting from June 30, 2023 -- for failing to recall all **defective devices determined to be harmful** to the health of those suffering from sleep apnea. **This was established by a ruling of the judges of the Court of Appeal of Milan**, XIV Civil Chamber, specialized in Company Law (& Enterprises matters), who with a Judgement that came yesterday upheld the Class Action, confirming it, brought by the Apnoici Italiani Association APS (Patients Association) and Adusbef APS (Consumer Association) against the forementioned Dutch multinational. In addition, the ruling enacting terms related to the recall of devices require the payment of "10 thousand euros for each day of delay" starting from today -- i.e. from the day following the issue of the conviction judgement-- which was fixed as a penalty. Moreover, the Judgment sentenced Philips SPA and the European distributor Respironics Deutschland GMBH to pay, jointly and severally, **Apnoici Italiani Association APS and Adusbef APS EUR 20.119,-** (twenty thousand euros) for their professional skills. Specifically, the medical devices at issue are Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, BiPAP A30/A40 Series, CPAP and Bi-level PAP.

A **victory for Apnoici Italiani Association APS and Adusbef APS**, who decided today to call a **press conference** at the ISMA conference room (in Via della Guglia, 69A), in Rome to announce the positive outcome of the 16-month lawsuit against the Dutch multinational. *"It is an important ruling because it is the first Class Action for an injunction brought in Italy (and Europe) to protect health and because two representative associations (patients and*

consumers) have managed to protect the right to health," commented **Luca Roberti, President of the Apnoici Italiani Association APS (Patients Association)**.

The effect of this judgement is that if a multinational fails to protect patients' safety, there is the possibility to proper enforcement through the imposition of a penalty. Therefore, by ceasing to make companies activity conditional on markets laws alone, the need to provide adequate health services to patients bestows value".

Attorney Antonio Tanza, Presidente di Adusbef APS (Consumers' Association) was satisfied with the ruling of the Court of Appeal of Milan, underlining *"the huge scope of the victory that has been achieved not only for apneic patients, but also for all consumers. The Class Action proves to be an effective and timely instrument that makes collective protection concrete, preventing prolonged exposure to health risks and establishing the individual right to safe treatment and care. We have proved that all patients could demand a quick replacement of defective devices. This result not only paves the way for patients' compensation, but also acts as a deterrent to prevent companies from neglecting the right to safety of each consumer in the future. I'm very proud of the path we've taken."*

Finally, commenting the Judgement, the **Attorney Stefano Bertone of the law firm Ambrosio & Commodo**, who in **September 2022** on behalf of the **Apnoici Italiani Association and Adusbef** had brought the Class Action **against the multinational** to speed up the recall and replacement of the devices, said: *"after 40 years of seeking compensation for damage that has already occurred, it is a huge satisfaction for **Ambrosio & Commodo** to play a new role in which we can, in part, prevent damage for the benefit of public health. However, the fact remains, more than 100,000 people have inhaled and ingested toxic substances which are potentially lethal, and are understandably shocked: the company shall be held to account for this before the courts in a new series of lawsuits/cases"*.

Sequence of Events

In June 2021, the Dutch multinational Philips had alerted the competent authorities about the danger related to certain medical respiratory devices, the use of which would have posed health risks to patients suffering from sleep disorders and neuro-muscular diseases. In particular, the problem concerns the degradation of the foam, used inside device to dampen the sound, that "releases particles and toxic substances either inhaled or ingested by the patient during treatment". Therefore, Philips had provided reassurance to solve the issue (by recalling, replacing, or repairing the devices involved) by December 2022. However, since this did not happen, the Court of Milan, upholding the Class Action filed by the representatives of 106 thousand users of Philips' unsafe medical respiratory devices, and in the light of the considerations also expressed by the Ministry of Health, had sentenced both Philips SPA and Respironics Deutschland --in its capacity as European agent of the US manufacturer Respironics-- to repair or replace (no later than 30 April) some of the sleep apnea devices deemed dangerous for patients. The Court established a penalty of 20 thousand euros "for each day's delay, in compliance with the Judgement and starting from the expiry of the deadline for the completion of the plan". The Class Action, the first of this kind, in the healthcare sector in Italy and Europe, was initiated at the behest of Apnoici Italiani Association and Adusbef. They were assisted by a pool of attorneys, coordinated by Attorney Stefano Bertone from the Lawfirm *Ambrosio & Commodo*. The Lawfirm had prepared the appeal asking to speed up the recall of those medical devices that "may have caused serious life-threatening injuries, permanent damage or medical interventions to avoid permanent damage".