

## Decision of

### **Laying down the specific conditions for the marketing, export, distribution, and holding for sale or distribution free of charge of medical devices manufactured and marketed by Philips**

The Director General of the French National Agency for Medicines and Health Products Safety (ANSM);

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended;

Having regard to Regulation (UE) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical device, as amended, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, in particular Articles 87, 89, 90, 93, 94, 97, 120, 122 and 123;

Having regard to Part 5 of the French Public Health Code (CSP), in particular Articles L. 5211-1, L. 5211-3, L. 5213-1, L. 5213-4, L. 5311-1, L. 5312-1 to L. 5312-4, R. 5211-1, R. 5211-4, R. 5211-5, R. 5211-17, R. 5211-21, R. 5211-22, R. 5211-24, R. 5211-34 and R. 5211-39;

Having regard to the Order of 15 March 2010 laying down the conditions of enforcement of the essential requirements applicable to medical devices, implementing Article R. 5211-24 of the CSP;

Having regard to the field safety notices issued by Philips dated 18 June 2021 and referenced FSN 2021-06-A and FSN 2021-05-A in relation to certain home ventilation and sleep apnoea treatment devices;

Having regard to the report prepared by PSN in accordance with the ISO 18562-3 standard on Philips Respireonics Dreamstation devices dated 24 May 2021 and forwarded by Philips to the ANSM;

Having regard to the report prepared by Philips Respireonics referenced QSP 7.3-283 dated 11 September 2021 and analysing volatile organic compounds (VOCs) and particles on Dreamstation devices;

Having regard to the Food and Drug Administration (FDA) publication dated 12 November 2021 in relation to the deviations observed during an inspection conducted on a manufacturing facility in the United States;

Having regard to the initial corrective action deployment schedule released by Philips dated 24 June 2021, revised on 5 August 2021 and 07 December 2021;

Having regard to the letter from Philips addressed to the ANSM dated 07 December 2021;

Having regard to the monthly status reports on the deployment of corrective action requested by the ANSM and forwarded by the distributor Philips France since September 2021;

Having regard to the meetings with the different stakeholders dated 17 and 24 June, 18 October and 14 December 2021;

Having regard to the hearings with Philips conducted during the meetings with the stakeholders dated 24 June 2021, 18 October 2021 and 14 December 2021;

Having regard to the medical device vigilance incidents in relation to continuous positive airway pressure (CPAP) devices and non-life support ventilators reported to the Agency;

Having regard to the draft health policy decision laying down the specific conditions for the marketing, export, distribution, and holding for sale or distribution free of charge of medical devices manufactured and marketed by Philips and its accompanying letter dated 12 January 2022 sent by the ANSM to Philips;

Having regard to the meeting held between Philips and the ANSM on 21 January 2022, as well as the response letter from Philips addressed to the ANSM on 28 January 2022, within the framework of the adversarial process;

Having regard to the e-mail from Philips dated 21 January 2022 forwarding the new corrective action deployment schedule to the ANSM;

Whereas from 26 May 2021, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices cited above has come into force, thereby repealing Directive 93/42/EEC cited above;

**Whereas**, however, Article 122 of Regulation (EU) 2017/745 cited above provides that for any medical device covered by a certificate issued under Directive 93/42/EEC cited above prior to 26 May 2021, the latter may remain in force until 27 May 2025 for this medical device;

**Whereas** Philips manufactures and markets the following products:

- Continuous positive airway pressure (CPAP) generators, called PR1 / SystemOne (Q-Series), DreamStation Pro, DreamStation Auto, DreamStation Expert, DreamStation BiPAP Auto and DreamStation GO;
- Ventilators with life support, called Trilogy 100 and Trilogy 200;
- And ventilators without life support, called DreamStation BiPAP autoSV, DreamStation BiPAP S/T and AVAPS, PR1/SystemOne autoSV, C-Series autoSV, S/T et AVAPS, OmniLab Advanced +, BiPAP A40 and A30;

**Whereas** these products, hereinafter referred to as "ventilation devices", are intended to provide patients with respiratory assistance, and therefore fall within the scope of the definition of a medical device set out in Articles L. 5211-1 and R. 5211-1 of the CSP;

**Whereas**, in addition, the aforementioned medical devices are supplied to patient-users by home healthcare providers;

**Whereas** in application of Articles L. 5211-3, R. 5211-17, R. 5211-34 and R. 5211-39 of the CSP, the marketing of these medical devices implies in particular that they meet the applicable essential safety and health requirements and that they are designed and manufactured in such a way as to achieve the performances claimed by the manufacturer;

**Whereas** point 1 of part I of Article 1 of the Order of 15 March 2010 cited above provides, under "General requirements", that medical devices must be designed and manufactured in such a way that their use does not compromise the clinical condition and safety of patients or the safety and health of users and that any risks associated with their use represent acceptable risks in view of the benefit provided for the patient and compatible with a high level of protection of health and safety;

**Whereas** Philips, on 10 June 2021, notified the ANSM that it was sending its customers a field safety notice relating to polyester-based polyurethane (PE-PUR) sound abatement foam, used in the aforementioned medical devices, which represents a potential risk of degradation and volatile organic carbon (VOC) emission; that this defect only applies to the aforementioned medical devices manufactured before 26 April 2021;

**Whereas** the foam may degrade into particles which may enter the air pathway of the device; these particles may therefore be ingested or inhaled by the user and/or emit certain chemicals;

**Whereas** the potential risks caused by exposure to the particles and/or chemicals caused by volatile organic compound emissions that have been identified are as follows: dizziness, irritation (skin, eyes, respiratory tract and nose), inflammatory response, headache, asthma, hypersensitivity, nausea/vomiting, adverse effects to other organs, toxic and carcinogenic effects;

**Whereas** in the light of the developments described above, the aforementioned medical devices, which are therefore liable to compromise the clinical condition and safety of patient-users in view of this defect, fail to meet the aforementioned essential requirement;

**Whereas**, accordingly, all necessary measures should be taken to protect the interests of patient-users of the aforementioned ventilation devices;

**Whereas** in the first instance, the analysis of the technical data indicates, that patient-users, in view of the very nature of the medical devices and the conditions treated, must continue their treatment despite the defect in the devices concerned; indeed, the risk induced by removing these ventilation devices would be greater than the potential risks induced by their use; it is nonetheless important that this use be of limited duration;

**Whereas** this limited duration must match the defective device replacement/repair schedule; during this period, the medical devices in compliance with European regulations manufactured by Philips must be marketed and distributed exclusively for the purpose of replacing or repairing a defective device currently in use;

**Whereas** also in the light of all the data available, some geographic areas might display a greater proportion of malfunctions and/or serious adverse effects than that in other areas; as such, it falls to Philips to prioritise the replacement and repair of defective ventilation devices in the light of the market surveillance data available;



**Whereas** in addition, ventilation devices covered by a CE mark having similar claims of use, manufactured by other manufacturers are currently available on the market; in this respect, home healthcare providers have signalled having started to replace ventilation devices by providing patient-users with other alternatives;

**Whereas in the second instance**, Philips committed to a defective device replacement and repair schedule, set out in the replacement plan in the version dated 5 August 2021, according to the following terms: replacement of 50% of the installed base of medical devices affected by the end of the first quarter of 2022, 75% in June 2022, and 100% in September 2022;

**Whereas** the initial schedule proposed met the two-fold objective of enabling the continuation of treatments while providing device replacement within a time-frame compatible with the risk assessment data available in relation to these non-conformities;

**Whereas**, however, in its letter dated 7 December 2021 cited above, Philips confirmed having difficulties keeping to the initial schedule and thus explained, on one hand, the low number of CPAP devices supplied since the summer of 2021, and, on the other, that as of 14 December 2021, no ventilators had yet been replaced by Philips;

**Whereas, furthermore**, by e-mail dated 21 January 2022, Philips forwarded a new version of the replacement schedule, now showing the following terms: released device quantities based on a rate of 34% of the installed base of medical devices affected by the end of the first quarter of 2022, 56% in June 2022, and 100% in December 2022;

**Whereas**, in the light of the data forwarded in support of this new version, a completion date at the end of 2022 would appear to be acceptable, provided that a strategy ensuring a 75% replacement rate to providers in June 2022 is maintained;

**Whereas** in the light of the above and in any case, the schedule and completion date announced must be accompanied by measures to ensure compliance;

**Whereas**, in addition, in the interests of public health, regular, transparent, substantiated information on Philips' actions and schedule is needed, by administrative authorities as well as patients and home healthcare providers; thus, it falls to the ANSM to conduct an extensive, exhaustive and regularly updated information campaign on the actions taken by Philips to replace or repair defective ventilation devices;

**Whereas**, in this respect, in order to inform patients, public opinion and home healthcare providers, it is therefore necessary for the ANSM to receive, at least every month, a status report on the actions taken by Philips to keep to the announced schedule to replace or repair the defective devices;

**Whereas, furthermore**, the FDA conducted an inspection on a Philips manufacturing facility in the United States; this inspection noted some deviations, reported by the FDA on 12 November 2021; Philips has not forwarded the information in its possession in relation to the deviations observed to the competent authorities;

**Whereas**, in the light of the above, in the interests of patients who have used the defective ventilation devices and with a view to setting up suitable follow-up where applicable, it is necessary to have clinical data collected under normal conditions of use on a significant number of patients;

**Whereas**, in addition, the implementation of the actions announced by Philips aimed at keeping to the announced schedule requires active input from home healthcare providers; it is important in particular, on one hand, that the latter provide exhaustive and transparent traceability of the supply of the affected products, and, on the other, that they take into account each patient's interests and circumstances in relation to their ability to adapt to an alternative or not;

**Whereas**, finally, some home healthcare providers have signalled having started to replace ventilation devices with other alternatives; therefore, it is necessary that they provide the ANSM with the precise number of defective devices replaced by Philips devices, as well as the precise number of defective devices replaced by devices from other manufacturers;

**Whereas**, in the light of the above, it is necessary to lay down the specific conditions for the marketing, export, distribution, and holding for sale or distribution free of charge of medical devices manufactured since 26 April 2021 and marketed by Philips;

## **DECIDES**

**Article 1** – The marketing, distribution, export and holding for sale or distribution free of charge of continuous positive airway pressure (CPAP) devices and ventilators manufactured since 26 April 2021 and marketed by Philips are subject to the following conditions;

- Philips is required to reserve the marketing and supply of the devices set out in the version of the replacement plan dated 21 January 2022 exclusively for the replacement and repair of defective ventilation devices present on the French market, until the entire installed base has been replaced or repaired;
- Philips is required to provide providers with a replacement of, or repair, defective ventilation devices present on the French market by any means necessary and according to the following schedule: 75% replacement in June 2022, and 100% in December 2022;
- Philips is required to prioritise the replacement or repair of defective ventilation devices present on the French market in line with market surveillance data.

**Article 2** – Philips is required to set up an independent epidemiological study aimed at fully assessing the cancer risk potentially caused by exposure to defective ventilation equipment, and to forward its preliminary findings to the ANSM within one year at the latest.

**Article 3** – Philips is required to provide the ANSM with monthly progress reports on the announced actions to replace or repair defective ventilation devices present on the market, which shall be subsequently published online on the ANSM website.

**Article 4** – Philips is required to update home healthcare providers regularly on the actions taken and provide them with any useful information for the timely replacement and repair of defective ventilation devices.

**Article 5** – Home healthcare providers are required to take all necessary measures, in particular in respect of traceability and information for users, to help implement Philips' corrective actions in accordance with the schedule announced by Philips.

**Article 6** – Philips is required to notify the ANSM of any useful information in relation to the medical devices covered by this decision, available prior to any public disclosure.

**Article 7** – Without prejudice to Article 1, and accounting for the medical circumstances of the patient assessed in particular in relation to their ability to adapt to another device, home healthcare providers may take any necessary measures to replace, in a timely manner, defective continuous positive airway pressure (CPAP) devices and ventilators, by replacement devices manufactured and marketed by Philips or by another manufacturer.

**Article 8** – Home healthcare providers shall provide the ANSM with monthly reports on the number of defective ventilation devices replaced, including by alternatives.

**Article 9** – The Director of Medical Devices, Cosmetics and In Vitro Diagnostic Devices and the Director of the Inspection Department are tasked with the implementation of this decision, which will be published on the ANSM website.

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