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Information for MDCG MD representative, ECommission, and Philips TF members

European Commission staff is allowed to share this message to MS WG and PMSV WG.

Dear Colleagues,

Following informations shared on january, 27th, about ANSM's action against Philips, I would like to inform you about the end of the adversarial process.

Please find attached the final decision signed by [REDACTED], and sent to Philips and French installers. The decision is in French, a translation will be available on monday.

Nevertheless, pdf is appropriate for OCR and web translation.

Best regards,

**Direction des dispositifs médicaux, des cosmétiques et des dispositifs de diagnostic invitro (DMCDIV) / Division for medical devices, cosmetics and in vitro diagnostic devices**

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Agence nationale de sécurité du médicament et des produits de santé

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courrier. Merci.

Avant d'imprimer, pensez à l'environnement.

>>> 27/01/2022 16:01 >>>

THE INFORMATION CONTAINED IN THIS EMAIL IS BEING PROVIDED TO YOU UNDER THE TERMS OF OUR CONFIDENTIALITY ARRANGEMENTS (MDCG Terms of reference art.10)

Information for MDCG MD representative and E Commission

Each MDCG representative and is allowed to share this message to its Philips TF representative under confidentiality

Dear Colleagues,

7 months after the publication of Philips's FSN regarding the recall of ventilators devices, ANSM remains unsatisfied with the implementation of this recall.

We would like to inform you that ANSM is considering to take a measure.

The aim of this decision is mainly reinforce Philips's commitments in the implementation of its corrective action and to formalize its responsibilities in this dossier. The main points of this decision are :

- to require Philips to follow the initially announced corrective action plan,
- to reserve exclusively the new devices available for replacement within the framework of this recall as long as it is not closed,
- request that an epidemiological study be conducted,
- to require Philips to send a monthly progress report to the ANSM and to send it any information relating to this recall before its publication.

This project is currently undergoing a contradictory phase with Philips and the home healthcare providers heavily involved in the implementation of this recall. Their feedback is expected before Saturday 29 January 2022.

Best Regards,

MD and IVDD liaison for French and European Institutions  
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