

Van: meldpunt@igj.nl
Aan: [_Dienstpostbus IGJ Utrecht](#)
Cc: [_Dienstpostbus IGJ ETL](#)
Onderwerp: SPOED MEDDEV nieuw 2106 2221, NL FSCA 2021-06-A to Dutch CA
Datum: maandag 14 juni 2021 14:51:31
Bijlagen: [image004.wmz](#)
[NL FSCA 2021-06-A - to Dutch CA.pdf](#)
[2021-06-A CPAP Recall Letter Unsigned.doc](#)
[NL FSN 2021-06-A Dutch.docx](#)
[Airpath Foam Degradation_HHE_PAP Systems_ER2241621v00.pdf](#)
[Appendix B - Non Life Sustaining - FSCA Form Supporting Data - 07JUN2021.xlsx](#)
[VOC HHE DreamStation1 platform ER 2242138 v01.pdf](#)
[NL FSCA 2021-06-A to Dutch CA.eml](#)
[5.1.2.e. ,Your reference number_NL FSCA 2021-06-A_Our reference number_IT 5.1.1.c .eml](#)

Bijgaand bericht inboeken MET SPOED svp. Dit ivm media-aandacht voor deze recall.

- Initial report bestaand in WPM: svp inboeken tbv Meldpunt, meldpuntteam Medische Technologie.

Ovb is verzonden.

IT: 5.1.1.c

Objectnummer: 5.1.1.c

DIV: graag document aan dit objectnummer en aan IT hangen

Met vriendelijke groet,

5.1.2.e. <meldpunt@igj.nl>

10-06-2021 10:50 Mailimport.: Sender: qandr_benelux@philips.com

Date sent: Jun 10, 2021 10:49 AM

To: "meldpunt@igj.nl" <meldpunt@igj.nl>

Subject: NL FSCA 2021-06-A to Dutch CA

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Philips Nederland B.V.

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image003.png

Philips Nederland B.V. | Postbus 90050 | 5600 PB Eindhoven | Nederland

Dear Madam/Sir,

Philips Nederland B.V. hereby reports FSCA 2021-06-A

Pursuant to article 89, paragraph 9, section b of the EU MDR (2017/45), Philips Respironics has requested BfArM to act as the Coordinating Competent Authority for this Field Safety Corrective Action in the EU. This is pending confirmation from BfArM.

Met vriendelijke groet / With kind regards / Sincères salutations,

On behalf of Q&R Benelux

5.1.2.e.

Post Market Surveillance officer

Philips Benelux

Tel: +31 (0)40 5.1.2.e., Email: qandr_benelux@philips.com

High Tech Campus 52. 1st floor
5656 AG Eindhoven, The Netherlands

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Connect with Philips

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