Norwegian Environment Agency

STERIS Ireland Limited
IDA Business and Technology Park. Tullamore
R35 X865 County Offaly
Ireland

Oslo, 08.02.2023

Your ref.:	Our ref.:	Contact person:
	2019/10691	Ingrid Ur Gjerde

Acceptance of administrative change to the authorisation for STERIS Ireland Limited – Vaprox biocidal product family NO-2019-0179

We refer to the notification dated 13 December 2022 for administrative changes to the authorisation of the biocidal product family Vaprox biocidal product family, R4BP 3 case number BC-CN082816-25.

Decision

The Norwegian Environment Agency hereby accepts the notified administrative changes to the product authorisation for Vaprox biocidal product family on the Norwegian market.

Terms and conditions for the change to the authorisation

The revised terms and conditions are described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case no. NO-0021697-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu). The terms and conditions as stated in the authorisation letter dated 29 November 2019 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the product label, an electronic copy of the revised label(s) for the relevant products shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no). The electronic copy of the label(s) must be submitted within three months from the date of this letter. Please mark the email with the authorisation number.

The approval is given in accordance with Article 6(4) of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR).

Norwegian Environment Agency

Background

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No 480.

The procedure for applications for administrative notifications to authorisations are set out in Article 6 of Regulation (EU) No 354/2013.

The notification concerns

STERIS Ireland Limited has notified administrative changes to the authorisation of Vaprox biocidal product family on the Norwegian market. The notified changes concerns addition of product manufacturer and change in wording of equipment name and model but not content of instructions, as referred to in Section 2 of Title 1 to the Annex to Regulation (EU) No 354/2013.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency considers the changes to meet the conditions in Title 1, Section 2 of Annex to Regulation (EU) no 354/2013 and therefore are acceptable.

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment.

An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen	Ingrid Ur Gjerde
Head of Section	Adviser