

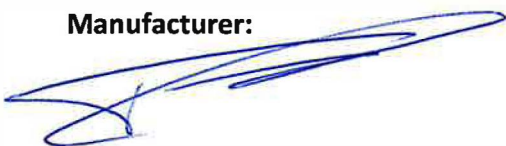
LETTER OF DESIGNATION

This letter officially designates Evondos Ltd (VAT ID: 494155665) as the 'UK responsible person' and 'Importer' for 'manufacturer' Evondos Oy (VAT ID: FI21758208). In this capacity, Evondos Ltd acts with the consent of Evondos Oy to perform the following tasks outlined in the UK MDR 2002 (as amended by the UK MDR 2019, UK MDR 2020 and UK MDR 2023 amendments):

- Registration of the manufacturer's medical device products with the MHRA prior to placing on the market
- Ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer.
- Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA.
- In response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device.
- Forward to the manufacturer any request by the MHRA for samples, or access to a device, and ensure that the MHRA receives the samples or has been given access to the device.
- Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated.
- Ensure post-market surveillance is carried out by the manufacturer
- Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the MHRA and, if applicable, the relevant notified body of that termination.

Both the manufacturer and UK responsible person shall comply with the Medicine and Medical Devices Act 2021. This designation is valid until June 30, 2028, unless terminated in writing by either party.

Manufacturer:



Frans Cromme
CEO, Evondos Oy

UK REP:

Mika Apell
Evondos Ltd

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Tämä asiakirja sisältää 1 sivua ennen tätä sivua

Dokumentet inneholder 1 sider før denne siden

Dette dokument indeholder 1 sider før denne side

Detta dokument innehåller 1 sidor före denna sida

MIKA PETRI APELL

Company - Yritys - Företag - Selskap - Virksomhed: Evondos Ltd

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Representative - Nimenkirjoitusoikeus - Firmateckningsrätt - Representant - Repræsentant

authority to sign

representative

custodial

asemavaltuus

nimenkirjoitusoikeus

huoltaja/edunvalvoja

ställningsfullmakt

firmateckningsrätt

förvaltare

autoritet til å signere

representant

foresatte/verge

myndighed til at underskrive

repræsentant

frihedsberøvende