CIBG
Minisrerie van Volksgezondheid,
Welzijn en Sporr

> Return address PO Box 16114 2500 BC Den Haag

Lotus NL B.V.
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2595 AA 's-Gravenhage

Farmatec

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Our reference:
CJBG-20203010

Attachments

Your request
18th June 2020

Correspondence should only be addressed to the return address, stating the date and reference of this letter.

Date: 22nd June 2020
Subject: notification of medical device class I

Dear Mr. Wei,

I hereby confirm receipt on June 18, 2020 of the notification of the medical device class I, that company SILVERFOX CORPORATION LIMITED, with European authorized Lotus NL BV, wishes to bring to the market as manufacturer in accordance with Regulation (EU) 2017/745 (MOR). The product is registered under the following reference. In all further correspondence regarding this product, I request that you quote the corresponding reference and keep it available when making telephone calls.

Disposable medical mask,Surgical mask
(no brand name) (NL-CA002-2020-52171)

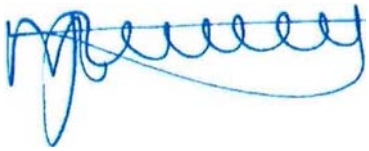
I would like to remind you that medical devices placed in the market as MDR must have a device indication system (UDI) [1] and that manufacturers, authorized representatives and importers must be registered[2] in the European database for European devices (Eudamed). Annex VI of the MDR contains the information to be provided with the registration. At the moment Eudamed is not in use yet, so it is sufficient for the above that you have notified your product in accordance with current laws and regulations.

Once Eudamed[3] is fully in use, the manufacturer or his authorized representative is expected to register the above device in Eudamed within 18 months.

[1] O.g.v . art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] wwww.camd-europe .eu / wp - content / uploads / 2018 / 0S / FAO MOR 180117 V I.O- I.pdf. See question and answer number 20.

I would also like to point out for the record that the registration of your communication regarding the delivery of the above-mentioned product is only an administrative act. This confirmation of receipt therefore does not include a decision regarding the qualification of the product in question as a medical device within the meaning of art. 1 WMH, nor regarding the classification in risk class I.

The Minister for Medical Care and Sport, on his behalf,
Department Head
Farmatec



Dr. M.J. van de Velde