

Livinguard AG
Pengpeng Cao
Bahnhofstrasse 12
6300 Zug

Bern, September 17, 2020

Your notification according to Art. 6 MedDO¹ dated 01.07.2020 regarding the placing on the market under MDR² of Livinguard Pro Mask and Livinguard Ultra Mask/ Medical Mask Type I or II

Acknowledgement of receipt

Dear Madam, dear Sir,

We have received the notification of the above-mentioned product and numbered it as shown below:

Notification No.: CH-202007-0004	Medical Device Class I
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The notification duty according to Art. 6 MedDO for this medical device has therefore been fulfilled.

Confirmation that the notification according to Art. 6 MedDO has been received does not, however, constitute either an attestation of conformity, or an officially examined registration, or an assessment of the quality of the device. It is a confirmation that Swissmedic has noted that the

¹ Medical Devices Ordinance of 17 October 2001 (as at 26 November 2017); SR 812.213

² Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

above mentioned Class I medical device has been placed on the market. This confirmation presupposes that the person or company placing the medical device on the market has carried out the investigations necessary to ascertain the product's conformity with MedDO and MDR.

Please be aware that you are responsible in particular for surveillance after the product has been placed on the market (Art. 83 ff. MDR) and for vigilance (Art. 87 ff. MDR), and that this confirmation does not absolve you of your obligation to register the product(s) in accordance with Art. 29 MDR or of your obligation to register in the European Database on Medical Devices (Eudamed) in accordance with Art. 31 MDR (registration of manufacturer, authorised representative and importer). You must complete these registrations within 6 months of the publication of the notice announcing that the Eudamed database is functional, add them to the declaration of conformity and communicate them to Swissmedic.

Yours sincerely,

Swissmedic, Swiss Agency for Therapeutic Products
Division Medical Devices Operations

A handwritten signature in blue ink, appearing to read "S. Carulli Amico".

Sabina Carulli Amico
Assistant