INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

ISS AG, Integrated Scientific Services, Robert-Walser-Platz 7, 2503 Biel

To whom it may concern

Biel, 6. October 2020

Market Access of Medical Masks in Switzerland

Dear receiver

The market access procedure for Medical Masks in Switzerland is basically as follows:

- The masks are classified as Class I Medical Device according to Art 5 of Swiss Medical Device Ordinance (MedDO).
- The manufacturer (in this case livinguard AG, Switzerland) is responsible for the conformity of the product according to the respective regulation (MedDO)
- Based on the requirements laid down in the named regulation, the manufacturer compiles a technical documentation and issues a declaration of conformity. With this declaration of conformity, the manufacturer confirms that the product is in conformity with the named regulation. The manufacturer shall provide a copy of this declaration of conformity upon request to its distributors.
- Prior to putting on the market the first medical device of Class I, livinguard has to notify the product to Swissmedic, according to Article 6 of MedDO. Basically this notification is valid for all "CE-countries" (EU Member States, EFTA, Switzerland and Turkey).
- Art. 7 of MedDO defines, that the product information has to be provided in German, French and Italian. Under specific circumstances (e.g. that the protection of patients, users and third parties is nevertheless ensured) the number of languages can be reduced.
- Once the notification is done, the product can be sold in Switzerland.
- In the future additional requirements will be applicable for the Swiss market, e.g. placing of a UDI-Code.

Sincerely

Hansjörg Riedwyl
CEO

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To whom it may concern

Biel, 5. October 2020

Market Access of Medical Masks in Europe

Dear receiver

The market access procedure for Medical Masks in Europe is as follows:

- The masks are classified as Class I Medical Device according to rule 1 of Annex VIII of the MDR (EU 2017/745)
- The manufacturer (in this case livinguard AG, Switzerland) is responsible for the conformity of the product according to the respective regulation (MDR, EU 2017/745)
- Based on the requirements laid down in the named regulation, the manufacturer compiles a technical documentation and issues a declaration of conformity. With this declaration of conformity, the manufacturer confirms that the product is in conformity with the named regulation. The manufacturer shall provide a copy of this declaration of conformity upon request to its distributors.
- Prior to putting on the market the first medical device of Class I, the manufacturer has to notify the product to the Competent Authority in the country where the manufacturer is situated (in this case Swissmedic). Basically this notification is valid for all "CE-countries" (EU Member States, EFTA, Switzerland and Turkey).
- Once the notification is done, the product can be sold in all CE-countries. Some restrictions:
  - A localization of Instructions for Use is necessary in most countries.
  - In some states, additional data has to be provided into a local database. If this is required, livinguard as Manufacturer will organize this entries in coordination with the local distributor.
- In the future (probably after 2022) the local databases will be replaced by the European Database "EUDAMED". So far EUDAMED is not ready yet for this functionality.

Sincerely

Hansjörg Riedwyl
CEO