REPUBLIC OF ESTONIA
MINISTRY OF SOCIAL AFFAIRS

Dr. Martin Weber
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Väljaminev kiri

Dear Dr. Martin Weber,

Thank you for your message and for your interest in contributing to the Estonian business environment, economy, and security. We understand that the regulatory process you have encountered has caused frustration and uncertainty.

The Republic of Estonia places high value on a transparent and lawful regulatory framework that ensures the safety of patients and users. The classification and placing on the market of medical devices is governed by Regulation (EU) 2017/745, which applies uniformly across all EU Member States. The aim of this regulation is to ensure high level of safety and efficacy for all medical devices sold in the European market and at the same time foster innovation.

The Estonian Medicines Agency (Ravimiamet), as the competent authority, is responsible for assessing medical devices in accordance with this regulation. It operates independently and is required to follow the legal framework established by the European Union. The Ministry of Social Affairs does not interfere with individual classification decisions.

In this particular case, the Estonian Medicines Agency has carefully reviewed the technical documentation, intended purpose, composition and the mode of action of SkinNeutrAll, which is also marketed under the commercial names BodyNeutrAll and PlumBodyNeutrAll, and compared it with the position of the German competent authority, BfArM. BfArM has determined the product in question to be a Class IIa medical device. Upon review, the Estonian Medicines Agency concluded that the product submitted for registration in Estonia as a Class I device is materially the same as that assessed by BfArM and therefore also Class IIa medical device. Therefore, in accordance with the applicable classification rules, the product must undergo a conformity assessment by notified body. Although this process may require more time and financial resources compared to Class I devices, it is necessary to ensure that only safe products are placed on the market.

Due to the reasons mentioned above, Estonian Medicines Agency has refused the registration of the product as Class I medical device. Should the company disagree with the decision, we encourage it to submit an appeal to the Estonian Medicines Agency with relevant explanations and evidence, as indicated in the official response from the Estonian Medicines Agency.

We would like to emphasize that if the product qualifies as a Class I device and is legally placed on the market in Germany under that classification, it can also be made available on the market in Estonia under the same conditions. Please note that the distribution of a Class I medical device in Estonia does not require notification in the Medical Devices Database (MSA). Alternatively, if the product is marketed in Germany as a Class IIa device with proper documentation and conformity assessment, there should also be no obstacles to its

distribution in Estonia provided that the required notification of distribution is submitted.

We appreciate your initiative and welcome your continued interest in supporting public health and the local market in Estonia.

Yours sincerely,

Anniki Lai
Vice Chancellor

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