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Teema: MedEnvoy: Terviseamet – Questions on Registration with Terviseamet and Notification of Medical Devices, In-Vitro Diagnostic Devices and Active Implantable Devices
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To whom it may concern,

Hope that you are doing well.

My name is Bill Broadley, and I am the primary contact for the European Authorised Representative Service at MedEnvoy Global B.V. (hereafter “MedEnvoy”).

MedEnvoy is a European Authorised Representative and Regulatory Importer company based in The Netherlands.
On behalf of MedEnvoy, I am reaching out to inquire about the possibility of registering with the national Competent Authority of **Estonia, Terviseamet.**

MedEnvoy wishes to perform notifications/registrations (hereafter “notifications/notify”) of medical devices, in-vitro diagnostic devices and active implantable devices (as applicable), on behalf of non-EU based manufacturers, where MedEnvoy is the Authorized Representative, of the aforementioned device categories (hereafter “manufacturers”), within your national database, Estonian Medical Devices Database (EMDDB).

MedEnvoy would like to clarify whether the above registration with you shall be possible, request any relevant permissions from you and understand the requirements for registering manufacturers’ devices on behalf of the manufacturers.

Please find the below the applicable questions where MedEnvoy requests further guidance:

1. Please can you clarify who is able to notify the aforementioned device categories within your national database from the following list of economic operators?
    a. **Legal Manufacturer** (EU or non-EU based)
    b. **European Authorised Representative** (mandated legal representative based in the EU for non-EU based manufacturers)
    c. **Importer** (who physically imports the devices)
    d. **Regulatory Importer** (who makes the initial placement of the device on the market and fulfils the responsibilities of importer as set out in Article 13 of the MDR)

e. **Distributor** (who markets/sells the device within the country)

2. Further, if the Regulatory Importer or European Authorised Representative can perform the notification of devices within your national database, is MedEnvoy, as a Regulatory Importer and/or European Authorised Representative based in The Netherlands, able to notify the manufacturer's devices on behalf of the manufacturer?
3. Additionally, would the registration of devices within EUDAMED (the European Commission's Database) be sufficient for Estonia's notification requirements at the current time?
    a. If the registration of devices within EUDAMED is **not** sufficient at the current time, please can you confirm if the notification of devices with Terviseamet are mandatory at this moment in time?
4. If national registrations are currently mandatory, please can you additionally clarify for which device categories it is necessary to register devices with Terviseamet?
    a. Our understanding is that the following device classifications must be notified within your national database.
        i. Class IIa Medical Devices;
        ii. Class IIb Medical Devices;
        iii. Class III Medical Devices;
        iv. Class B, C or D In-Vitro Diagnostic Medical Devices.
    b. Please can you confirm if the above understanding is correct?
5. Please can you confirm whether there shall be any applicable costs for registering with Terviseamet and notifying the manufacturer's devices within the EMDDB?
    a. If applicable costs are involved, please can you provide MedEnvoy with some further reference material and/or estimation of the incurred costs for both MedEnvoy's registration as an Actor and the registration of a manufacturer's devices?
6. Finally, if available, please provide MedEnvoy with an estimation of the applicable timelines that may apply to the processing of MedEnvoy's registration as an Actor with Terviseamet as well as the notification of a manufacturer's devices within EMDDB?

Please let me know if you require any further information or clarification regarding the above questions.

Additionally, please inform us if these questions should be directed to an alternative email address.

Finally, MedEnvoy understands that in order to gain access to the website, MedEnvoy shall forward its IP address to abi@tehik.ee with an access request – please can you confirm that this understanding is correct?

Many thanks for considering the above questions, MedEnvoy looks forward to hearing back from you.

Kindest regards,

Bill Broadley

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