APPLICATION FOR AN EXEMPTION FOR PLACING A MEDICAL DEVICE ON THE MARKET OR PUTTING ONE INTO SERVICE

In accordance with Article 59 of Regulation (EU) 2017/746 on medical devices (MD) / Article 54 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVD) and Section 58 of the Medical Devices Act (719/2021), the Finnish Medicines Agency Fimea may grant a fixed-term exemption for placing a medical device on the market or putting one into service, even if the conformity assessment procedure for the device has not been carried out in accordance with the MD Regulation or the IVD Regulation.

The completed and signed form with its attachments is submitted using Fimea's Secure Mail Service (https://secmail.fimea.fi/) to derogations@fimea.fi.

1A. Applicant

Organisation	Address
Email address	Contact person for the application
Contact person's email address	Contact person's telephone number

Applicant's representative (if applicable)

Organisation	Address
Email address	Contact person for the application
Contact person's email address	Contact person's telephone number

1B. Manufacturer (if other than applicant)

Company	Address
Email address	Contact person for the application
Contact person's email address	Contact person's telephone number

1C. Medical device

Name of the device	EMDN code, if available
Model, product number or UDI	**Device manufacturer**

Risk class of the device according to the MD/ IVD regulation

◯ MD I ◯ MD IIa ◯ MD IIb ◯ MD III	◯ MD Is ◯ MD Im	◯ IVD A ◯ IVD B ◯ IVD C ◯ IVD D	◯ IVD As

Intended use of device

Is the device available on the market outside the EEA? ◯ Yes ◯ No

If yes, where?

☐ Americas ☐ Asia/Oceania ☐ Middle East/Africa

Has the notified body previously performed a conformity assessment of the device for the intended use covered by this application?

◯ Yes ◯ No

If yes, under which legislation has the conformity assessment been conducted?

◯ MDD ◯ MDR ◯ IVDD ◯ IVDR

Specify when the device is expected to be CE marked. (dd.mm.yyyy). Please add relevant correspondence with the notified body as attachments to the application.

Briefly explain how the device is necessary for protecting public health or alleviating or treating a patient's disease or injury. Please present a statement from clinicians using the device as attachment to the application.

Are there similar CE marked devices already on the market? ◯ Yes ◯ No
Please attach documented evidence

Briefly describe how the device differs from other similar CE marked medical devices on the market. Please attach documented evidence.

Are there alternative treatments (medicinal products, medical devices or other) available? Please attach documented evidence
◯ Yes ◯ No

Briefly describe the evidence showing that the device fulfils the relevant general safety and performance requirements. Please provide GSPR (with relevant appendices) according to Annex I to MD / IVD Regulation as attachment.

2. Application

Specify the time needed for exemption (dd.mm.yyyy – dd.mm.yyyy).

Has an exemption been applied for the device in other EU Member States?
◯ Yes ◯ No

If yes, please indicate the Member States where an exemption has been applied for and the status of the application:

☐ AT ☐ BE ☐ BG ☐ CH ☐ CY
☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES
☐ FR ☐ GR ☐ HR ☐ HU
☐ IE ☐ IS ☐ IT ☐ LI ☐ LT
☐ LU ☐ LV ☐ MT ☐ NL ☐ NO
☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK ☐ TR

Approval received from the following Member States:

Denial received from the following Member States:

Application under review:

Attachments to the application (* for additional guidance, please see below

- [ ] 1. GSPR (with relevant appendices) according to Annex I to MD / IVD Regulation
- [ ] 2. Statement on the need for the exemption from clinicians using the device or equivalent statement
- [ ] 3. Correspondence with the notified body
- [ ] 4. Planned timeline for CE marking
- [ ] 5. Decisions (both positive and negative) from other Member States, if available
- [ ] 6. Instructions for use of the device
- [ ] 7. Evidence that there is no similar CE marked medical device on the market
- [ ] 8. Other, please specify:

I affirm that the information and documents delivered with this application above are correct and that all information requested has been provided.

Signature

Name

Position

(* 1. GSPR - A checklist of how the general safety and performance requirements set out in Annex I of the MD/IVD Regulation, including standards and common specifications, are fully or partially met, and a description of the solutions to meet general safety and performance requirements to the extent that these standards or common specifications are not met or are only partially met or are missing.

2. Independent statement from clinicians working in Finland who use the device in their work, or other equivalent statement from a Finnish healthcare institution, the Ministry of Social Affairs and Health or an agency or institution under its administrative branch

7. Clearly documented evidence that there is no similar CE marked medical device on the market.

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