**Et bilde som inneholder skjermbilde, sort

Automatisk generert beskrivelseApplication for exemption from the conformity assessment procedure (CE-marking) of a medical device**

Submit your application to the Norwegian Medical Products Agency: meddev-no@noma.no

|  |  |  |
| --- | --- | --- |
| **Part I – filled in by the manufacturer** | | |
| Name and address of manufacturer | Contact person for the application, name and address | |
| Device name | The role of the contact person (manufacturer/authorized representative/distributor/importer) | |
| Generic name of the medical device | Telephone number of the contact person | |
| The GMDN-code of the device, if applicable | E-mail address of the contact person | |
| The intended use of the device | | |
| Indicate which requirements in the regulation of medical devices the application applies to | | |
| Is the device authorized for marketing/use outside the EEA? Attach relevant documentation, e.g. FDA approval    Is the device available on the market in other EEA/EU-states? Enter any number of device units. | | |
| Specify the number of devices the application applies to | | |
| Specify the time period for which the application applies to | | |
| Specify when the device is expected to be CE marked. Attach relevant correspondence with the notified body and timeline for CE-marking | | |
| How will the device(s) be handled after the end of the derogation period? | | |
| Has the device been used before in clinical trials or performance studies (IVD)? | | |
| Describe how the device differs from other similar devices already on the market | | |
| Explain the documentation that provides support for the device to be used safely and correct for both the patient and other users. The documentation should also contain information that supports a risk/benefit analysis. | | |
| Details on Vigilance or recall issues to date | | |
| List any attachments to the application. This can be, for example, a risk analysis, risk management reporting, instructions for use, etc. If the device has an EC-certificate (for relevant risk class) and a Declaration of Conformity, this must always be attached. | | |
| Date, name and title | | Signature |

|  |  |  |
| --- | --- | --- |
| **Part II – filled in by the user/clinician** | | |
| Name and address of user/clinician | Contact person for the application, name and address | |
| Name and address of manufacturer | Telephone number of the contact person | |
| Device name | E-mail address of the contact person | |
| How many patients does the application apply to | | |
| Justification based on a specific need of one particular patient or targeted patient group | | |
| Indicate what measures have been taken to find an alternative device that meets the requirements of the regulations | | |
| Explain why any available CE-marked device(s) or are not a suitable alternative for the patient(s). Describe possible consequences if the patient(s) cannot access the device(s) | | |
| Date, name and title (business manager or similar) | | Signature |

First time published: 26.05.2021

Updated: 23.01.2024