CONSENT PROCEDURE: DEROGATON REQUEST FOR A MEDICAL DEVICE/ IVD

You have received this document because you would like to apply for derogation for a medical device (MD) or vitro diagnostic medical device (IVD). We request that you take note of the procedure below.

TERMS AND CONDITIONS DEROGATION APPLICATION

In the interest of public health, and/or the safety and health of patients, the Minister of Health, Welfare and Sport (hereafter: VWS) is authorized, on the basis of the Medical Device Act (hereafter: Wmh), Article 8, fourth paragraph, in combination with Article 4, second paragraph, to grant a derogation from the provisions of Article 59, first paragraph, of Regulation (EU) 2017/745 and the provisions of Article 54, first paragraph, of Regulation (EU) 2017/746.

The Health and Youth Care Inspectorate (hereinafter the inspectorate) advises the Minister of VWS on whether or not to grant a derogation. The Minister of VWS will decide on your application partly on the basis of this advice. If a derogation is granted, it is always temporary and strict conditions apply to which the applicant for the derogation and/or the manufacturer of the MD/IVD must comply.

A derogation will only be granted if the following three criteria are met, namely if:

- without a derogation an **unacceptable risk** will arise for patient care in the Netherlands and;
- **no equivalent alternative** is available and;
- the manufacturer has made it plausible that the device is **safe** and that the MD/IVD meets the quality and safety requirements as described in the relevant legislation and regulations.

We ask that you verify if the above described criteria apply to your request, before submitting your application.

SUBMITTING YOUR APPLICATION:

If you are of the opinion that your application meets the abovementioned criteria, you must submit this filled in form (without the documentation behind points 1 to 17 listed below), to the CIBG via:CIBGOntheffingenMedischeHulpmiddelen@minvws.nl

After you receive a confirmation of receipt and reference number from the CIBG you must send your request for derogation, including the confirmation of receipt from the CIBG; this completed form; and the documentation listed below after points 1 to 17 to the inspectorate via: meldpunt@igj.nl. To send your documents securely you can use https://igj.rijkscloud.nl.

Attach your documentation to the e-mail with in the subject line: "Derogation request article 59/54 + reference number+ name manufacturer + name of the MD/IVD and product group".

If applicable to your case, you must inform your authorised representative of your derogation request.

The Inspectorate will substantively assess the content and documentation of your request and advise the Minister of VWS on whether or not to grant the derogation.

Please provide the following documents point by point (and numbered) and make clear, with the names of the documents, to which point the delivered document belongs:

1. If applicable: when you, as the applicant are already registered in EUDAMED your SRN.
2. An overview of the products for which you, as the applicant, apply for derogation **and** which have already been placed on the market in the Netherlands.
3. The reason that you as, an applicant, need a derogation and/or why the CE certificate could not be extended in time.
4. An overview of the competent authorities within the EU from whom you, as the applicant, have applied for a similar derogation, including the decision and reasoning of the relevant competent authorities.

5. The expected date that the CE certificate will be issued by the notified body, including the timeframe confirmed by the notified body.
6. A sales overview of the MD/IVD'S that fall under the application for derogation and that have been sold in the Netherlands in the past 2 years. Among which:
    - the numbers per type of product, including customers/care providers, and;
    - the stock situation in combination with usage figures resulting in the number of days of stock at the most critical care providers.
7. If applicable: if your CE certificate has already expired, proof that customers / healthcare institutions have been informed about the invalidity of the CE certificate.
8. A statement/ declaration drawn up and motivated by at least one (1) healthcare provider or user concerning the essential importance of the use of the MD /IVD.
9. An explanation of what you, as the applicant, believe the risks are with regard to patient safety if the requested derogation is not granted.
10. An estimate of the affected patient population in the Netherlands.
11. Tick the corresponding box below to what the effect will be on the patient if no derogation is granted.
    ☐ Minor injury or minor reduction in quality of life of a temporary nature
    ☐ Limited injury or limited reduction in quality of life of an irreversible nature
    ☐ Serious injury or serious temporary loss of quality of life of a temporary nature
    ☐ Serious injury or serious impairment of quality of life of an irreversible nature
    ☐ Life-threatening injury or unacceptable reduction in quality of life
    ☐ Other:
12. Tick the corresponding box below regarding the duration of the impact on the patient if no derogation is granted:
    ☐ 1 day ☐ 1 week ☐ 1 month ☐ more than a month ☐ permanent
13. An overview of the Dutch customers (resellers and/or healthcare providers) with whom you, as the applicant, expect that these risks will occur if the requested derogation is not granted, including the timeline in which these risks are expected.
14. An explanation of whether the MD/IVD for which a derogation is requested can be replaced without additional risk in the short term by MD/IVD from other manufacturers, including a motivation.
15. If applicable: An overview of the outstanding non-conformities that the notified body has found in the products for which you, as an applicant, apply for a derogation, including the expected end date when the non-conformities have been removed/ solved.
16. A copy of the relevant CE certificate.
17. A confirmation that the products covered by this application for derogation have not been adapted/changed after the CE certificate has expired and will be produced and delivered under exactly the same conditions in the event of a possible derogation.

If necessary, the inspectorate may request additional information.

POSSIBLE CONDITIONS WHEN A DEROGATION IS GRANTED

When the Minister of VWS decides to grant a derogation, it is always subject to strict conditions. Conditions for a derogation may include, but are not limited to:

- The temporary nature of the derogation
- (Reporting) obligations for the use of the MD/IVD for which an derogation has been issued.
- (Reporting) obligations for the sale of the MD/IVD for which an derogation has been issued.
- An active obligation to report on the progress of the CE assessment by a notified body.
- An obligation to inform users that a derogation has been issued for the MD/IVD.

AFTER YOUR REQUEST

The CIBG and the Inspectorate aim to complete the processing of your application in a timely manner. The time required for this depends, among other things, on the completeness of your application and the time required to obtain additional information about your application.

We would like to bring to your attention that the final decision on your derogation application will be in the Dutch language.

WITHDRAWAL OF YOUR APPLICATION

If you, as an applicant, do not wish to proceed with your request for derogation, you can send a request to withdraw the application to the CIBG via:
CIBGOntheffingenMedischeHulpmiddelen@minvws.nl

If no documentation is provided, we trust that you do not wish to proceed with the application and we consider this request as not submitted.

DECLARATION

You have read this document and completed it truthfully.

You submit a request to grant a derogation from the provisions of Article 59, first paragraph, of Regulation (EU) 2017/745 or the provisions of Article 54, first paragraph, of Regulation (EU) 2017/746.

Information to be completed about product:

Product name:

Catalogue number:

Intended purpose of the MD/IVD:

Manufacturer information to be filled in:

Name Manufacturer:

Country manufacturer:

KVK-number:

Manufacturer intends to CE mark the MD / IVD (yes/no):

Final decision on derogation needs to be send to:

Name applicant:

E-mail address:

Address (street), house number, postal code:

Country applicant:

Company and Function applicant:

Submission date :