PROCEDURE: MDR ARTICLE 97 (1) REQUEST FOR A MEDICAL DEVICE/ ACTIVE IMPLANTABLE MEDICAL DEVICE

You received this document because you would like to apply for the procedure regarding article 97 (1) of the MDR for legacy devices for which the MDD or AIMDD certificate[1] expires before the issuance of a MDR certificate, in conjunction with MDCG 2022-18. We request that you take note of the procedure below.

MDR Article 97(1) Market surveillance – Other non-compliance
TERMS AND CONDITIONS

In December 2022 the MDCG Position Paper on the application of Article 97 (1) MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate (hereafter: MDCG 2022-18). As delineated in MDCG 2022-18, the competent authority (CA) of a member state can, in accordance with Article 94 MDR, carry out an evaluation of devices suspected of presenting an unacceptable risk or other non-compliance.

Article 97 (1) of the MDR enables CAs to require a manufacturer, or its authorised representative to bring a non-compliance to an end within a reasonable and clearly defined period, with the effect that the devices continue to be placed on the EU-market. The non-conformity concerns an MDD/AIMDD certificate of the devices that has expired or expires before the issuance of the required certificate in accordance with the MDR. Specific conditions apply: the conformity assessment by the Notified Body and the certification of devices according to the MDR will not be finalised before the MDD or AIMDD certificate expires, and the device does not present an unacceptable risk to health and safety of patients or the public health. These conditions will ensure that the conformity of the devices concerned is established as soon as possible under the conditions set by the CA, while limiting as much as possible the impact on the supply of safe and effective devices to patients and healthcare providers.

The application of Article 97 (1) MDR is always temporary and the period by when the manufacturer should bring the device into compliance will be proportionate to the extent/severity of the non-compliance in accordance with Article 97(1) MDR read in conjunction with MDCG 2022-18.

Article 97 (1) in conjunction with MDCG 2022-18 **only applies** to the following conditions listed in MDCG 2022-18: Please check whether these conditions are applicable before you (manufacturer or authorised representative) submit your application.

☐ Your legal base as a manufacturer or Authorised Representative is situated in the Netherlands.
☐ The MDD/AIMDD certificate of the devices has expired or expires before the issuance of the required certificate in accordance with the MDR.
☐ Devices fall under the scope of Article 120(3) MDR after 26 May 2021 (DOA of the MDR); considered legacy devices[2];
☐ Devices are 'in transition' from the MDD/ AIMDD to the MDR; **OR**
☐ Devices for which despite reasonable efforts undertaken by the manufacturer to obtain certification under the MDR, the relevant conformity assessment procedure involving a notified body has not been concluded in time.

Article 97(1) in conjunction with MDCG 2022-18 does **not** apply to:
- devices for which the certificate issued under the MDD or AIMDD has been suspended or withdrawn by the notified body. The Directive's certificate must have been or must be valid at the date of its expiry.
- devices that have undergone a significant change in design or intended purpose after 26 May 2021 within the meaning of Article 120(3) MDR as further explained in MDCG 2020-3.

[1] In this document, the word certificate should be understood as certificate or certificates

[2] Legacy Devices, Article 120 paragraph 3 (MDCG 2021-25) Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021. It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

SUBMITTING YOUR APPLICATION:

If you declare that your devices meet the criteria mentioned above, you must complete and submit this form and provide the following statements, that apply to **each medical device** on the application. Subsequently send the completed form, annex I, containing a list of all applicable medical devices, and the documentation in points A to C to the CIBG via: CIBGartikel97@minvws.nl.

Please attach your documentation to the e-mail with in the subject line: "Article 97 application request + name manufacturer". The Competent Authority (IGJ) will subsequently assess the content of your request. After the assessment of your application, the IGJ will draw up a formal decision.

Please provide the following information:

1. Information to be provided in this table by the applicant:

If the Applicant is a **Manufacturer** based in the Netherlands:	
• Company name of legal entity:	
• Address of legal entity:	
• Single Registration Number (SRN):	
• Name, function and contact details of responsible executive who signs the application letter:	
• Name, function and contact details of the contact person for this application:	
If the applicant is an **Authorised Representative** based in the Netherlands:	
• Company name of legal entity:	
• Address of legal entity:	
• Single Registration Number (SRN):	
• Name, function and contact details of responsible executive who signs the application letter:	
• Name, function and contact details of the contact person:	
• Name of legal manufacturer of the medical devices for which the application is submitted:	
• Name, function and contact details of a contact person for the manufacturer:	
If the applicant is an **Manufacturer** based outside the EU:	
• Company name of legal entity:	
• Address of legal entity:	
• Single Registration Number (SRN):	
• Name, function and contact details of responsible executive who signs the application letter:	
• Name, function and contact details of the contact person:	
• Name of the Authorised Representative based in the Netherlands:	
• Name, function and contact details of a contact person for the Authorised Representative:	

2. Please provide a list of medical devices for which the application is made. Provide this list in **tabulated form** as **Annex 1** to your application. In Annex I you should provide the following basic information for **each** medical device:

For every medical device:	
• Commercial name/trade name:	
• Type of device:	
• GMDN/EMDN code:	
• Unique identification by UDI-DI or MD nomenclature code classification according to MDD or AIMDD:	
• Classification according to MDR:	
• Notified Body name:	
• Notified body identification number MDD/AIMDD certificate:	
• Identification number of MDD/AIMDD certificate under which it was marketed under the MDD/AIMD:	
• Expiry date of MDD/AIMDD certificate under which it was placed on the market:	
• The date from which the device is not or will not be in compliance with MDR:	
• The reason the device is not or will not be in compliance with MDR:	

DOCUMENTATION TO SUBMIT WITH YOUR REQUEST

A. Most recent notified body's audit report, with regard to information about potential safety-related shortcomings identified by the relevant notified body during the last surveillance audit, and confirmation regarding satisfactory resolution; or the absence thereof. The certificate and devices to which the audit report applies must be clearly identified.
B. Most recent report or PSUR by manufacturer containing all relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions, or the absence thereof. The certificate and devices to which the report or PSUR applies must be clearly identified. • If no such report is yet available (i.e., for Class I and Class IIa devices), a statement of the manufacturer that no incidents, serious incidents and/or field safety corrective actions have been observed with the medical device concerned from analysis of available PMS data.
C. The most recent CE-certificate issued by a notified body in accordance with MDD or AIMDD (not suspended nor withdrawn).

STATEMENTS

You submit a request under the provisions of Article 97(1), first paragraph of Regulation (EU) 2017/745 Thereby you declare[3] that (please tick all applicable boxes):

2	Statements to be provided by applicant. **<u>For each medical device and for each certificate concerned</u>**, the applicant and/or manufacturer declares that:
☐	The CE-certificate covering the medical device concerned was issued by a notified body in accordance with MDD or AIMDD and is (or was) valid at the expiry date of that certificate (not suspended nor withdrawn).
☐	The device is (or was) at the time of expiry of the MDD/AIMDD certificate a 'legacy device' within the meaning of MDCG 2021-25[4].
☐	*If the device is NOT (or was NOT) at the time of expiry of the MDD/AIMDD certificate a 'legacy device' within the meaning of MDCG 2021-25[5].* the manufacturer qualifies as SME considering the definition given in https://single-market-economy.ec.europa.eu/smes/sme-definition_en. AND that the notified body was not designated for the MDR in time and/or that it cannot process the application before the expiry date of the directive certificate due solely to limited capacity. OR that reasonable and appropriate attempts were undertaken to obtain certification by notified bodies, appropriately designated for the medical devices in question, in a timely manner; and these notified bodies cannot process the application before the expiry date of the directive certificate due solely to limited capacity.
☐	The device is not or will not be in compliance with the MDR before expiry of the MDD/AIMDD certificate, and that the applicant formally requests the Competent Authority of the Netherlands to perform an evaluation of the device concerned as described in MDR art. 94. Applicant also requests the Competent Authority of the Netherlands to impose all necessary measures in accordance with MDR art. 97(1), in conjunction with MDCG 2022-18 and its current intervention policy MDR/IVDR.
☐	There is or will be no significant change(s) in design or intended purpose since 26 May 2021 and until the end of non-compliance as described in MDR art. 120 (3) and MDCG 2020-3.
☐	The applicant, the manufacturer and the medical device will comply with all applicable provisions in the MDD/AIMDD until the end of the non-compliance.
☐	The applicant, the manufacturer and the medical device will comply with all applicable provisions in the MDR, particularly with regard to PMS, vigilance and market surveillance as described in MDR art. 120 (3) and MDCG 2021-25.
☐	To the best knowledge of the applicant, there is no unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health, as evidenced by: • A valid MDR QMS certificate by a notified body; and/or a valid ISO 13485 certificate **AND**

[3] Please note that the IGJ will randomly request supporting documentation for declarations made amongst all applicants in the declarations section.

[4] Legacy device Article 120 paragraph 3 (MDCG 2021-25)
Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021.
It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

[5] Legacy device Article 120 paragraph 3 (MDCG 2021-25)
Devices placed on the market after DoA MDR (May 26, 2021) until May 26, 2024 under the following conditions:
- class I MH Directive 93/42/EEC (MDD), with an EC declaration of conformity drawn up before 26 May 2021 and who must go through a conformity assessment procedure under the MDR at a notified body under the MDR;
- devices with a valid CE certificate for Directive 90/385/EEC (AIMDD) or 93/42/EEC (MDD) before 26 May 2021.
It concerns a valid certificate at the time of expiry, which has not been revoked or suspended.

	• The most recent notified body's audit report, identified no information about potential safety-related shortcomings identified during the last surveillance audit, and/or confirmed satisfactory resolution thereof. • The most recent report or PSUR by manufacturer containing all relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions, identified no information about potential safety-related shortcomings. • for Class I and Class IIa devices where no PSM report or PSUR is available: no incidents, serious incidents and/or field safety corrective actions have been observed with the medical device concerned from analysis of available PMS data.
☐	The applicant and/or manufacturer will proactively and without delay inform the CA about any safety-related corrective or preventive actions, serious incidents and all other new information relevant for the assessment of the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
☐	The applicant and/or manufacturer will inform all known distributors and, if applicable, importers about the non-compliance and measures to end the non-compliance.
☐	The applicant and/or manufacturer will proactively and without delay inform the CA if the manufacturer decides to end the EC-conformity assessment procedure with the Notified Body.
☐	The applicant agrees to the publication of these measures on the website of the Competent Authority in order to proactively inform end-users.
☐	The applicant has not filed, at the same time, an application under MDR Article 59.1 at the competent authority.

AFTER YOUR REQUEST

After you have submitted your request, you will receive a confirmation of receipt and reference number from the CIBG.

The CIBG and the IGJ 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. Only applications that are fully complete, including all required documentation, and all appropriate statements made by the applicant, will be taken into consideration.

We would like to bring to your attention that the final decision on your Article 97(1) application will be in the English language.

WITHDRAWAL OF YOUR APPLICATION

If you, as an applicant, do not wish to proceed with your request for Article 97(1), you can send a request to withdraw the application to the CIBG via: CIBGartikel97@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.

Please note that the IGJ will randomly request supporting documentation for declarations made amongst all applicants in the declarations section. The IGJ expects that the requester/manufacturer will always have this documentation available and can provide it instantly when requested by the competent authority.

You have read this document and completed it truthfully.

Name and signature:

Final decision on Article 97 needs to be sent to:

Name applicant:
E-mail address:
Address (street), house number, postal code:
Country applicant:
Company and Function applicant:
Submission date: