Request by a Manufacturer / Authorised Representative in accordance with MDCG-2022-18[[1]](#footnote-1),[[2]](#footnote-2)

This form should be completed by the manufacturer or their European authorised representative for application of MDCG-2022-18 to devices with certificates expiring under the Medical Device Directives[[3]](#footnote-3),[[4]](#footnote-4). **Only certificates that were valid at the date of expiry (i.e. were not subject to a suspension, restriction, etc.) and have already expired or are expiring within three months of the submitted request will be considered by the HPRA**. The completed form must be submitted with required documentation and accompanying fee ([**fee code 473**](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.hpra.ie%2Fdocs%2Fdefault-source%2Fpublications-forms%2Fforms-applications%2Ffin-f0018-fee-application-form-for-human-products-v29.xlsx%3Fsfvrsn%3D74&wdOrigin=BROWSELINK) per certificate) to the Medical Devices department of the HPRA by email to devices@hpra.ie.

application Details

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| --- | --- |
| Manufacturer name |       |
| Manufacturer address |       |
| Authorised representative details (if applicable) |       |
| Authorised representative address |       |
| Contact name |       |
| Contact email |       |
| HPRA registration number (if applicable) |       |
| Notified body name |       |
| Notified body number |       |
| Notified body contact details |       |
| Device(s) commercial name(s) |       |
| Device class[[5]](#footnote-5)  |       |
| Notified body certificate number |       |
| Notified body certificate expiry date\*\*Note – The HPRA will consider requests where the certificate has expired, or the expiry date is within the next three months. |       |
| Have you completed an Article 97 request with another national competent authority? |       |
| If yes, please provide national competent authority details. |       |
| Have you lodged an application with a notified body for a new certificate under the MDR? |       |
| If yes, please provide the name of the notified body and proof of the initial application (e.g. initial correspondence, application form, or similar) (including dates). |       |

documentation to provide with application

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| *Please provide the following documentation:** Copy of expired, or due to expire, certificate(s) issued by a notified body in accordance with MDD or AIMDD
* Confirmation from the notified body that issued the certificate(s) that such certificate(s) were not subject to any restrictions or conditions, such as suspension or withdrawal at the date of expiry
* Copy of the most recent notified body audit report, including details of non-compliances and non-conformities identified
* Reason for changing to a new notified body under MDR (if applicable)
* Copy of declaration of conformity issued in accordance with MDD or AIMDD
* Letter from manufacturer with:
	+ confirmation and commitment that there has been no significant change in design or intended purpose since 26 May 2021 and similarly, that there will be no significant changes until the end of non-compliance under Article 97, MDR; and
	+ confirmation of continuous application of MDR requirements in relation to PMS, vigilance and market surveillance as per Article 120, MDR including commitment by manufacturer to proactively inform the HPRA about any potential safety-related issues; and
	+ confirmation that any potential safety-related shortcomings identified during recent audits or other conformity assessment activities have been satisfactorily resolved, following CAPA implementation and verification of effectiveness
* Copy of letter from notified body[[6]](#footnote-6) with:
	+ confirmation that an application for MDR certification has been accepted and that a contract has been signed by both parties in accordance with Annex VII, part 4.3; and
	+ details of the estimated timeline to complete the conformity assessment procedure; and
	+ commitment to inform the HPRA about major safety-related shortcomings identified during conformity assessment, including audit
* Copy of recent notified body’s audit report:
	+ in particular with regard to information about potential safety-related shortcomings identified by notified body during last audit and confirmation regarding satisfactory resolution
* Vigilance, market surveillance, or other information to prove that there is no unacceptable risk to the health or safety of patients, users or other persons, or other aspects of the protection of public health, in the form of:
	+ post-market surveillance report (including data concerning incidents, serious incidents and ongoing field safety corrective actions); and
	+ complete Annex I - List of ongoing field safety corrective actions (FSCA)
* Copy of issued MDR QMS certificate or, if not yet issued, confirmation by manufacturer of adaptation to MDR QMS requirements
* Copy of letter to distributors/importers about non-compliance to MDR

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declaration

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| --- | --- | --- | --- | --- | --- | --- |
| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, representing the manufacturer, am aware that permission is being sought for continuing to place the above-listed medical devices into the European market in accordance with Article 97 of the Medical Devices Regulation EU 2017/745 as per MDCG-2022-18.I have made all relevant data relating to the use of this device in this context, with specific attention to the risk/benefit analysis, available to the HPRA.  I confirm that none of the above-listed devices has incurred any significant change in design or intended purpose since 26 May 2021, and commit to not implement any significant change until the end of the non-compliance. The manufacturer confirms that it is in the process of seeking certification for the above listed devices under Regulation EU 2017/745, and commits to pursuing an end to the non-compliance without any undue delay. To the best of my knowledge, none of the above-listed devices poses an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health. There is no adverse trend in incidents or serious incidents, which could pose an unacceptable risk and the devices covered by this request continue to meet the requirements of the Medical Devices Directive 93/42/EEC / Active Implantable Medical Devices Directive 90/385/EEC as appropriate. In addition, all requirements listed in Regulation EU 2017/745, in relation to post market surveillance, vigilance and market surveillance, as well as those in relation to the application of a quality management system, have been, and will continue to be, implemented. I confirm our commitment to proactively inform the HPRA of any safety related corrective or preventive actions, or any change in the safety profile of the devices concerned.

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| --- | --- |
| Signature:       | Date:        |
|  |  |
| Print name:        | Title/position:        |

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Annex I. List of ongoing field safety corrective actions (FSCA)

Please provide a list of ongoing field safety corrective actions (FSCA) for each device with the HPRA reference, your reference, the International Medical Device Regulators Forum (IMDRF) Annex D code that better describes the investigation conclusion for each FSCA, and a short summary overview of the FSCA (i.e. background and type of action), by completing the below table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Device** | **HPRA Reference** | **Manufacturer Reference** | **IMDRF Annex D - Investigation conclusion or summary of root cause** | **Summary overview of FSCA (i.e. background and type of action)** |
|   |  |  |  |  |
|   |  |  |  |  |
|  |  |  |  |  |

1. [MDCG 2022-18](https://health.ec.europa.eu/system/files/2022-12/mdcg_2022-18_en_1.pdf) - MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate. [↑](#footnote-ref-1)
2. Please note that MDCG-2022-18 is a bridging solution until the validity of certificates are extended. For more information see [Commission proposal COM(2023)10 of 6.1.2023](https://health.ec.europa.eu/system/files/2023-01/mdr_proposal.pdf). [↑](#footnote-ref-2)
3. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [↑](#footnote-ref-3)
4. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [↑](#footnote-ref-4)
5. 5 Note: this process is not applicable for Class I medical devices, except for Class I medical devices that are sterile, have a measuring function and/or are reusable surgical instruments. [↑](#footnote-ref-5)
6. According to [MDCG 2022-18](https://health.ec.europa.eu/system/files/2022-12/mdcg_2022-18_en_1.pdf) ‘*In duly justified cases, the CA may waive this condition, in particular where the following conditions are all met: (i) the manufacturer is a SME, (ii) MDD or AIMDD certificate of that SME manufacturer had been issued by a notified body not (yet) designated under the MDR, (iii) the SME manufacturer can demonstrate that it has undertaken reasonable efforts to apply to a considerable number of relevant notified bodies and that their application has not been accepted due to limited notified body capacity*’. [↑](#footnote-ref-6)