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| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** |
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| **Type of application :** |
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| **Part 1 – to be filled in by the manufacturer** |
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| **Manufacturer** |
| Name : |  |
| Address : |  |
| Information regarding the contact person for the manufacturer |
| First and last name : |  |
| Phone number : |  |
| e-mail : |  |
| **Distributor** |
| Name : |  |
| Address : |  |
| Information regarding the contact person for the distributor |
| First and last name : |  |
| Phone number : |  |
| e-mail : |  |
| **Information regarding the device** |
| Trade name : |  |
| Model : |  |
| Serial number : |  |
| Description of the device : |  |
| If the device is a companion diagnostic, provide information on the accompanying therapy. |  |
| **Similarity with available devices** |
| Are there similar CE-marked devices? |  |
| If so, why can’t they be used? |  |
| If not, what are the differences with devices / drugs traditionally used for the same medical conditions?  |  |
| Please also provide information on benefit / risk analysis, risk identification, risk estimation and how these risks have been addressed, as well as information supporting a benefit analysis. |
| **Information regarding FDA approval for the device** |
| Has the device been approved by the FDA? |  |
| If so | Please provide the documents regarding this approval. |
| What is the complete scope ? |  |
| **Information regarding clinical investigations / performance evaluations for the device** |
| Is the device undergoing clinical investigation / performance evaluation? |  |
|
| If so (ongoing or finished) | Please provide the documents regarding this investigation. |
| What is the study title ? |  |
| What is the complete scope ? |  |
| If the clinical investigation is still ongoing, is it located in Belgium ? |  |
|
| If so, why can’t the patient / patient sample be included in the study ? |  |
| SignatureName | **Date :** |

**Part 2 – to be filled in by a physician – can be find on the next page.**

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| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** |
| **Part 2 to be filled in by a physician** |
| **physician** |
| First and last name : |  |
| Phone number : |  |
| e-mail : |  |
| Name of the hospital : |  |
| Address of the hospital : |  |
| Service of the hospital : |  |
| **Patient** |
| Initials: |  | Sex : |  |
| Age category : |  |
| Has the patient been notified that the device is not placed on the market / put into service in accordance with the European legislation? |  |
| If not, what are the reason ? |  |
| Information on the medical conditions of the patient : |  |
| Medical reasons justifying the application : |  |
| Consequences to patient’s condition if the device is not used: |  |
| Is a surgical intervention planned?  |  |
| If so, which date ? |  |
| I, the undersigned, ......................................................, * take full responsibility for the use of the device requested and will make a complete follow-up of the patient and notify all incidents and / or side effects related to the use of the device.
* certify that, unless there is a justified reason, the patient has been notified that the device is not placed on the market / put into service in accordance with European legislation.
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| SignatureName : | **Date :** |

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| When applying for compassionate use of a non-CE marked medical device/IVD, the FAMHP collects and processes personal information. This data processing is necessary for the reasons set out in Articles 6, §1, c), e) and 9, §2, i) of the [General Data Protection Regulation](https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:32016R0679&from=EN) (EU-RGPD).Your data protection rights:By contacting us by email at mailto:derogation.meddev@fagg-afmps.be, you can at any time:- Obtain confirmation that your personal data is or is not being used and how it is being used (Article 15 of the GDPR).- Rectify your personal data (article 16 of the GDPR)- Exercise your right to limitation (Article 18 of the GDPR).- Exercise your right to object (Article 21 of the GDPR)Only written requests will be considered |