|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** | | | | | | | | |
|  | | | | | | | | |
| **Type of application :** | | | | | | | | |
|  | | | | | | | | |
| **Part 1 – to be filled in by the manufacturer** | | | | | | | | |
|  | | | | | | | | | |
| **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 ? | | | |  | | | | |
| Signature  Name | | | | | | | **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. | | | | | | |
| Signature  Name : | | | | | **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 |