**IVD medical devices**

**notification form**

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| **A Administrative data** | |
| Type of notification |  |
| First notification |  |
| Change of information |  |
| Previous notification number (in case of change): | |
| Enter text. | |

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| **B Information on submitter** |
| Manufacturer |
| Authorized representative |
| Other (please identify the role): |
| Enter text. |

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| **C Manufacturer information** |
| Name  Enter text. |
| Contact name  Enter text. |
| Addess  Enter text. |
| Country  Enter text. |
| Phone  Enter text. |
| E-mail  Enter text. |

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| **D Authorised representative information** |
| Name  Enter text. |
| Contact name  Enter text. |
| Addess  Enter text. |
| Country  Enter text. |
| Phone  Enter text. |
| E-mail  Enter text. |

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| **E Submitter information (if differ from C. or D.)** |
| Name  Enter text. |
| Contact name  Enter text. |
| Addess  Enter text. |
| Country  Enter text. |

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| Phone  Enter text. |
| E-mail  Enter text. |

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| **F IVD medical device / devices information** | |
| **IVD medical device name or group name:**  Enter text. | |
| **Brief description and intended use of IVD medical device / group of devices:**  Enter text. | |
| Risk classification    **IVDD**  IVD-other  List A, Annex II  List B, Annex II  For self-testing | **IVDR**  Class A  Class B  Class C  Class D |

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| **G EC Certificate information (if applicable)** |
| Notified Body name:  Enter text. |
| Notified body ID-number (4 numbers):  Enter text. |
| EC Certificate number:  Enter text. |
| Date of issue and expiration date:  Enter text. |

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| **H Comments:** |
| Enter text. |

I affirm that the information given above is correct to the best of my knowledge.

# Signature field

Signature

Date