Request for Classification of a Human Health Product

When completing this form, refer to the HPRA *Guide to* *Definition of a Medicinal Product,* the HPRA *Guide to the Classification of a Medical Device* and to the accompanying documentation as requested in section D. If there is not enough space in the boxes provided, please attach any relevant documentation to this form.

Complete sections A, B, D, E and F of the form for all products. In addition, complete section C of the form for medical devices or *in-vitro* diagnostics.

Section A: Administrative information

|  |  |
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| 1. Date of submission for review of classification
 |       |
| 1. Name and address of organisation making this application
 | Name:      Address:       |
| 1. Applicant’s contact details
 | Contact person:      Telephone number:      Email address:       |
| 1. Manufacturer’s name and address including site where the manufacture of the product is taking place (where different from 2 above)
 | Name:      Address:       |
| 1. Manufacturer’s contact details
 | Telephone number:      Email address:       |
| 1. If the manufacturer is not based in an EU/EEA Member State, name and address of authorised/local representative
 | Name:      Address:       |
| 1. Telephone number and email address of local EU/EEA representative
 | Telephone number:      Email address:       |

Section B: Product/device information

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| --- | --- |
| 1. Name of product/device
 |       |
| 1. Proposed classification of product/device
 | [ ]  Medicinal product [ ]  Cosmetic[ ]  Medical device [ ]  IVD[ ]  Other (please specify):      *Please note that a justification for the proposed classification must be provided (see section D).* |
| 1. Description of product/device (state all forms and presentations)
 |       |
| 1. Composition of product

 (with specific reference to the quantities and roles of the ingredients/constituents which contribute to the product function)  |      *N.B. For herbal products include full details about the botanical species and the plant part used. Where extracts are used, provide details such as the extraction solvent, extraction method and drug-extract ratio.*  |
| 1. Intended use/purpose of product or device
 |       |
| 1. Mechanism of action (i.e. how does the product work?) Please attach supporting information.
 |       |
| 1. Is the product or device novel? If so, in what way?
 |       |
| 1. Is there a new intended use/purpose (for existing product or device)?
 |       |
| 1. What are the product or device label claims?
 |       |
| 1. Has the classification of the product or device been reviewed by any other regulatory agency? If so, what was the outcome of that review?
 |       |
| 1. Has the product or device been approved by any other regulatory agency? If so, which agency?
 |       |
| 1. Are there similar products or devices on the market?
 |       |

**Section C: Additional Information for Medical Devices/*In-vitro* diagnostics only**

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| 1. Proposed class of device

 *Please tick appropriate box.* | Medical device (MDR 2017/745)[ ]  Class I[ ]  Class I sterile[ ]  Class I measuring function[ ]  Class IIa[ ]  Class IIb[ ]  Class III*In-vitro* diagnostic medical device (98/79/EC)[ ]  General[ ]  Annex II, List B[ ]  Annex II, List A[ ]  Self-test, not Annex II*In-vitro* diagnostic medical device (IVDR 2017/746)[ ]  Class A[ ]  Class B[ ]  Class C[ ]  Class D |
| 1. Proposed classification rule
 |       |
| 1. Is the product an accessory to a device? If so, what device?
 |       |
| 1. Is the product a custom-made device?
 |       |
| 1. Is the product a system or procedure pack?
 |       |
| 1. Is the product stand-alone software?
 |       |
| 1. Is this part of an IVD kit?
 |       |
| 1. Does the product contain nanomaterials or viable/non-viable tissues/cells of human/animal origin? Please provide details.
 |       |
| 1. Has the device classification been reviewed by a notified body? If so which notified body and what was the outcome of the review?
 |       |
| 1. Is the device intended for use by a patient, an untrained user or a healthcare professional?
 | [ ]  Patient[ ]  Healthcare professional[ ]  Healthcare assistant[ ]  Untrained user Other:       |

**Section D: documentation to be attached (for all requests)**

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| *Please tick each box to confirm that the documentation has been attached.*[ ]  Applicant’s justification for the proposed classification including any references (e.g. scientific literature) to support the classification[ ]  Product label, package leaflet (if applicable) and instructions for use[ ]  Promotional/advertising material including reference to websites  (Please list website addresses here:      ) |

**Section E: Fees**

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| Refer to HPRA *Guide to Fees* on the HPRA website for fees and methods of payment.If paying by cheque, the cheque should be made payable to the Health Products Regulatory Authority.Enter fee submitted: €       |

section F: declaration

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| **Signed on behalf of** **<company name>**I certify that the information and documentation submitted with this application is correct in detail and all the information requested has been supplied.**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**      **Print name:**       **Title/position:**        |