

**Application Form for Consultation by a Notified Body on an Ancillary Medicinal Substance in a Medical Device**

**Send this form with accompanying documentation to:** [**med-udstyr@dkma.dk**](mailto:med-udstyr@dkma.dk)

|  |  |
| --- | --- |
|  | 1. Date of request |
|  | Click here to write date |

|  |
| --- |
| 1. Application details |
| 2.1 Name/type of medical device  Click here to write text |
| 2.2 Ancillary medicinal substance(s)  Click here to write text |
| 2.3 Strength/amount in medical device  - If different variants, please add them here:  Click here to write text |

|  |
| --- |
| 1. Notified Body |
| 3.1 Name  Click here to write text |
| 3.2 Person authorized to communicate on behalf of notified body  Click here to write text |
| 3.3 Street address  Click here to write text |
| 3.4 Postal code and city  Click here to write text |
| 3.5 Country  Click here to write text |
| 3.6 E-mail  Click here to write text |
| 3.7 Telephone number  Click here to write text |
| 3.8 Billing address (if different from above)  Click here to write text |
| 3.9 CVR number for billing address (if Danish)  Click here to write text |
| 3.10 Purchase order number (if relevant)  Click here to write text |

|  |
| --- |
| 1. Applicant for device approval (for CE-marking) |
| 4.1 Name  Click here to write text |
| 4.2 Contact person  Click here to write text |
| 4.3 Address  Click here to write text |
| 4.4 Country  Click here to write text |

|  |
| --- |
| 1. Manufacturer of the ancillary medicinal substance |
| 5.1 Name  Click here to write text |
| 5.2 Contact person  Click here to write text |
| 5.3 Address  Click here to write text |
| 5.4 Country  Click here to write text |
| 5.5 E-mail  Click here to write text |
| 5.6 Telephone number  Click here to write text |
| 5.7 EU-GMP verification should always be provided for the medicinal substance manufacturer  EU-GMP verification |
| 5.8 If an Active Substance Master File is submitted a letter of access should be provided  Letter of access Applicant´s and Restricted part of the Active Substance Master File (ASMF)    Not applicable |
| 5.9 If more than one manufacturer is applied for, add the additional manufacturer details here:  Click here to write text |

|  |
| --- |
| 1. Classification of application |
| New active substance (NAS) in Denmark |
| Known active substance within a new therapeutic area |
| Known active substance within an established therapeutic area |
| Tissues or cells of human origin (non-viable) |
| Device itself composed of substance absorbed by or locally dispersed in the body |
| MDR-reassessment |
| Transfer from current competent authority to the DKMA |

|  |
| --- |
| 1. For initial consultations |
| 7.1 Ref no assigned by the DKMA for the request of scientific consultation  Click here to write text |
| 7.2 Date of presubmission meeting (if applicable)  Click here to write text |

|  |
| --- |
| 1. For MDR-reassessments and/or Transfer from current NCA to the DKMA |
| For a product that has previously been consulted on under MDD a new scientific consultation (an MDR-reassessment) is needed prior to the first certification under the MDR-legislation. |
| Full documentation package is submitted |
| Copies of all Assessment reports by previously consulted NCA is submitted |
| List of changes since the initial consultation is submitted |
| No changes since the initial consultation (certificate submitted) |
| DKMA was the initially consulted NCA |
| 8.1 Transfer from NCA (to be specified):  Click here to write text |
| 8.2 Planned transfer date:  Click here to write text |
| 8.3 – DKMA Ref no for previous scientific consultation  Click here to write text |

|  |
| --- |
| 1. Signature |
| 9.1 Signature  Click here to write text |
| 9.2 Name of company  Click here to write text |
| 9.3 Name in printed letters  Click here to write text |
| 9.4 Date (YYYY-MM-DD)  Click here to write text |