

**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**

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

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| 1. Application details
 |
| 2.1 Name/type of medical deviceClick 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 |

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| 1. Notified Body
 |
| 3.1 NameClick 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 cityClick here to write text |
| 3.5 CountryClick here to write text |
| 3.6 E-mailClick here to write text |
| 3.7 Telephone numberClick 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 |

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| 1. Applicant for device approval (for CE-marking)
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| 4.1 NameClick here to write text |
| 4.2 Contact personClick here to write text |
| 4.3 AddressClick here to write text |
| 4.4 CountryClick here to write text |

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| 1. Manufacturer of the ancillary medicinal substance
 |
| 5.1 NameClick here to write text |
| 5.2 Contact personClick here to write text |
| 5.3 AddressClick here to write text |
| 5.4 CountryClick here to write text |
| 5.5 E-mailClick here to write text |
| 5.6 Telephone numberClick 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 |

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| 1. Classification of application
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| [ ]  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 |

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

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| 1. For MDR-reassessments and/or Transfer from current NCA to the DKMA
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| 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 consultationClick here to write text |

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