**Request for meeting with the Danish Medicines Agency for advice on the legislation and regulations related to medical devices**

***Please note that the replies to all questions must be as specific and detailed as possible. The Danish Medicines Agency does not offer specific advice on topics such as classification, concrete product development, authorisation, commercial strategies, or matters where the Danish Medicines Agency may make a decision, or similar situations. If this is the case, the agency will refer the inquirer to private advisers. Please note that regulatory advice is not a service available to consultants and other private advisers.***

|  |  |
| --- | --- |
| **Date of application:** |  |

***Submit the form to mu-reg.advice@dkma.dk***

|  |  |
| --- | --- |
| **Company/applicant:** | |
| **Contact:** |  |
| **Address:** |  |
| **Email:** |  |
| **Telephone number:** |  |
| **CVR number (Danish applicants only):** |  |
| **Product name(s)**  *Required field* |  |
| **Which legislation would you like guidance on?**  *Required field* | MDR  IVDR |
| **Do you want guidance on AI ​​Act?** | Yes  No |
| **Is the product a medical device or in vitro- diagnostic (IVD) medical devices?**  *Required field* | Yes  No |
| **Is the product an AI system?**  *Required field* | Yes  No |
| **Description of the product(s)**  *Be as specific as possible (consider inserting a link)*  *Required field* |  |
| **Are you a manufacturer, importer, distributor or other?**  *Required field* |  |
| **Name of manufacturer**  *Required field* |  |
| **Risk class**  *Required field* |  |
| **Insert the manufacturer’s intended purpose**  *Required field* |  |
| **Is the product CE marked as a medical device?**  *Required field* |  |
| **Name of notified body**  *Required field* |  |
| **Has advice been requested before?** | Yes  No |
| Reference no. |  |
| Date of previous advice: |  |
| **Advice is requested about:** | |
| Please describe briefly the area in which you seek advice (e.g. clinical investigation, registration requirements, CE marking, etc.)  *Required field* |  |
| **Advice form:** |  |
| Meeting  Teleconference | |
| **Proposed meeting date(s):**  *At least 14 days' notice must be given from the time the Danish Medicines Agency has received all relevant information.* |  |
| **List of proposed questions:**  *Required field – all questions must be described specifically.* | |
| Question: | Own considerations and answers to questions (including their basis): |
|  |  |