**Consultation procedure for a medicinal substance added to a medical device**

**Notified body decision**

|  |  |
| --- | --- |
| **1. Name of product** | **2. Consultation reference number***(Insert number allocated by ANSM)* |
|  |  |
| **3. Notified Body***(insert name, address, telephone and e-mail address of contact person)* | **4. Applicant seeking device approval***(insert name and address)* |
|  |  |
| **5. Decision of notified body** |
| **❒ The EC certificate was issued****❒ The EC certificate was not issued***(Please comment as appropriate)* |
|  |
| **Signature Date****Capacity in which signed:** |

**Please complete all boxes and return form to:**

ANSM

DMCDIV – dmcdiv@ansm.sante.fr

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