Mod 2a – Application form

For supplementary consultation by a notified body on an ancillary medicinal substance used in a medical device

This application form is to be used for an application for a Supplementary consultation procedure for a scientific opinion on any change (which could have an effect on the quality, safety or usefulness of the drug substance in the device) of an ancillary medicinal substance used in a medical device submitted to Italian Medicine Agency (AIFA) in accordance with Regulation (EU) 2017/745.

A combined form is acceptable for a range of strengths/concentrations of an ancillary medicinal substance in a medical device/range of medical devices (e.g. different strengths of medicinal substance) and for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance from the same manufacturer (give information successively, where appropriate).

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Declaration and signature

Name of medical device(s): <**Name**>

Ancillary medicinal substance(s): <**Ancillary**>

Strength/concentration of ancillary medicinal substance(s): <**Strength/concentration**>

Presentation(s) of ancillary medicinal substance(s) as part of the medical device: <**Presentation(s)**>

Notified Body (applicant): <**Name**>

Person authorised for communication on behalf of the notified body: <**Name**>

Medical device manufacturer: <**Medical device manufacturer**>

It is hereby confirmed that the Notified Body submits an application for a Supplementary Consultation Procedure for a Scientific Opinion on changes of the ancillary medicinal substance in accordance with the proposals given below.

It is declared that:

- ☐ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
- ☐ The change do not adversely affect the usefulness of the ancillary medicinal substance(s) as part of the medical device(s) as initial verified by Notified Body;
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- ☐ Fees have been paid according to the AIFA rules.

On behalf of the Notified Body:

_____

Signature(s)

Name: <**Name**>

Function: <**Function**>

Place and date <**Place**> <**DD-MM-YYYY**>

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1. Type of application

This application concerns

☐ **Supplementary Consultation** (following a change made to the ancillary medicinal substance incorporated in a medical device which could have an effect on the quality, safety or usefulness of the medicinal substance in the device)

Provide details on the previous consultation procedure

Italian Medicine Agency (AIFA) procedure number *(when known to the Applicant)*: *<number>*

☐ **minor amendment**

☐ **major amendment**

1.1 Change(s) concern(s) *(tick all changes applicable)*

☐ **Quality**

☐ **Non-clinical**

☐ **Clinical**

☐ **Other**

2. Notified body, contact person, medical device manufacturer

2.1 Notified body

Name of notified body: *<Name>*
Contact person: *<Contact person>*
Address: *<Address>*
Country: <Country>
Telephone: *<+XX XX XXXX XXXX>*
Fax: *<+XX XX XXXX XXXX>*
e-mail: *<e-mail address>*

2.2 Person/company authorised for communication on behalf of the notified body during the AIFA consultation procedure

Name of contact: *<Contact person>*
(if different to 2.1 above, attach letter of authorisation for communication on behalf of the notified body)
Address: *<Address>*
Country: *<Country>*
Telephone: *<+XX XX XXXX XXXX>*
Fax: *<+XX XX XXXX XXXX>*
e-mail: *<e-mail address>*

2.3 Medical device manufacturer(s)

Name: *<Name>*
Address: *<Address>*
Country: *<Country>*
Telephone: *<+XX XX XXXX XXXX>*
Fax: *<+XX XX XXXX XXXX>*
e-mail: *<e-mail address>*

3. Description of the ancillary medicinal substance

3.1. Name of the medicinal product(s) containing the ancillary medicinal substance(s)

<N/A> *Insert 'not applicable' if this application only concerns an active substance used as ancillary medicinal substance*
<Name of the medicinal product(s)>

3.2. Name of the ancillary medicinal substance(s)

<Name>

Note: Only one name should be given for each substance in the following order of priority: INN (The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant), Ph. Eur., National Pharmacopoeia, common name, scientific name.

3.3. Intended purpose of the ancillary medicinal substance(s) in the medical device

<Text>

3.4. Manufacturers of the medicinal product(s) / ancillary medicinal substance(s)

For each manufacturer involved

Name: *<Name>*
Address: *<Address>*
Country: *<Country>*
Telephone: *<+XX XX XXXX XXXX>*
Fax: *<+XX XX XXXX XXXX>*
e-mail: *<e-mail address>*

Brief description of functions performed:

<Description>

Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites

4. Medical device(s) concerned by this application

If this list is very extensive (more than one page) it may be added as annex to the application form.

4.1. Name of the medical device(s)/range of medical device(s)

<Name>

4.2 Short description of the medical device/range of medical device(s)

<Text>

4.3 Intended purpose of the medical device/range of medical devices(s)

<Text>

4.4 Route of administration (*Use current list of standard terms – European Pharmacopoeia where applicable)*

<Text>

4.5 Strength/concentration and presentation(s) of the ancillary medicinal substance in the medical device

- **Strength/concentration**: *<Text>*
- **Presentation(s)**: *<Text>*

4.6 Packaging components of the medical device/range of medical devices, including description of material from which it is constructed

(*Use current list of standard terms - European Pharmacopoeia where applicable*)

5. Precise scope and background for change

(*Include a description and background of all the proposed changes, with a justification for its proposed classification*

<Text>

PRESENT Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level	**PROPOSED** Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level
<Text>	*<Text>*

6. Other Applications under revision, if applicable

<Text>

7. Documentation provided *(description of all documentation provided)*

<Text>

<u>NOTE</u>: In relation of the variation proposed add the relevant information from the Application form for initial Consultation – Mod 2

(for example for a change Manufacturers of the ancillary medicinal substance(s) add all the information from the section 2.4 with the relevant annexed document).

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