Mod 1 – Briefing Document Template
Scientific explanation for qualification

Notified Body (applicant)	<Name>
Medical device manufacturer	<Name>
Medical device	<Name>
Ancillary medicinal substance	<INN> <Common name>

Evaluation for DM of class III according to Annex IX chapters I, II, III:	
Consultation procedure for certification / renewal of certification	☐
Supplementary Consultation	☐

To be filled in case of Supplementary Consultation: Describe the 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

Medical Device previously classified according to rule 13, annex IX of directive 93/42 / EEC *give a reason in case of negative answer*	Yes	No
	☐	☐
For the medical device previously classified according to the rule 13, annex IX of directive 93/42 / EEC, indicate any changes made to the technical documentation (in line with the MCDG 2020-12 Guideline):		
to the ancillary medicinal substance	Yes	No

in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐
To the manufacturing process	Yes	No
in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐i
the way the substance is incorporated into the device	Yes	No
in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐
to design, manufacturing of the device which could influence the quality, safety or usefulness of the ancillary substance, *in case of positive answer indicate the modification and the section of the reference technical documentation*	Yes ☐	No ☐
changes in the documentation of the device due to the new MDR requirements, for example in clinical evaluation, which have a bearing on the quality, safety usefulness of the ancillary substance. *in case of positive answer indicate the modification and the section of the reference technical documentation*	Yes ☐	No ☐
changes in the assessment of the device	Yes	No
in case of positive answer indicate the modification and the section of the reference technical ocumentation	☐	☐

any administrative changes related to	Yes	No
in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐
names or addresses	Yes	No
in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐
documents layout	Yes	No
in case of positive answer indicate the modification and the section of the reference technical documentation	☐	☐
other	Yes	No
please specify	☐	☐

A. Scientific explanation that the action of the medicinal substance incorporated in the medical device is only ancillary to that of the device in line with the MDCG 2022-5 April 2022

1. Description of medical device

- Type of product, ancillary medicinal substance, brief description, principal intended action:
<Text>
Make reference to medical device / medicinal product definitions

- Intended use: <Text>

- Product presentation / composition: <Text.>
Description of the product (e.g. Quantitative and qualitative composition, route of administration and/or mode of action, pharmaceutical form (where relevant)

2. Method by which the principal intended action is achieved

Combination product medical device part(s) + ancillary medicinal substance(s)	Principal intended action according to applicant[1]	Reference to MDCG 2022-5 guidance, April 2022[2]
Medical device part(s)	**Principal action:** *<title that clearly describes the action>* **Scientific explanation** (brief):	*Refer to relevant section of the Guideline and to respective example*
Ancillary medicinal substance(s)	**Ancillary action: *<title that clearly describes the action>*** **Scientific explanation** (brief):	*Refer to relevant section of the Guideline and to respective example*
Add more lines as needed		

[1] Provide cross-reference to supportive scientific information in Section B.

[2] In addition reference to other regulatory texts can be made where relevant.

3. Regulatory status (if existing)
Status in EU member states (including EEA countries) and outside EU if applicable.
Provide examples of similar products that have already been marketed in EU or outside EU.

4. Current use
Description of how medical device is used alone or in combination with the ancillary medicinal substance (in EU or outside EU).

5. Other relevant aspects
<Text>

B. Supportive scientific information

This section is the most important to reach a conclusion on the ancillary action of the medicinal substance in the medical device. In particular scientific information demonstrating the ancillary nature of the medicinal substance (in line with the demarcation guideline, MDCG 2022-5 guidance April 2022) in the combination product has to be provided).

Scientific information should cover:

(*This list is not exhaustive and is only intended for guidance*)

- The mode of action of the components (medical device and medicinal product) on their own and in the combination product.

- Any reference / summaries of pre-clinical or clinical experience/trials with the combination product / medicinal product alone / device alone / similar combination product.

- Explanation why the medicinal substance is added to the medical device: identification of those patients that would benefit from this combination product versus medical device alone.

- Consideration of the potential risks associated with the addition of the medicinal substance to the medical device (immune reactions, carcinogenicity, etc.)

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Signature(s)
Name: <**Name**>
Function: <**Function**>
Place and date <**Place**> <**DD-MM-YYYY**>

Agenzia Italiana del Farmaco Via del Tritone, 181 - 00187 Roma (+39) 06.59.78.401 www.aifa.gov.it