

## Proposal for a Notified Body Opinion Template

### Scope of the position paper:

The current position paper is intended to provide a template for the opinion of the Notified Body (NBOp) with respect to the conformity of device part of a combination product to the GSPRs of Annex I of the Medical Device Regulation 2017/745 and in accordance with article 117 of MDR 2017/745.

This template is a proposal for the content of a notified body opinion (NBOp) and is created in order to obtain a harmonised reporting method. It does consider the minimum content for a notified body opinion as proposed in Annex I and Annex II of EMA/CHMP/QWP/BWP/259165/2019 Guideline on the quality requirements for drug-device combinations. The information contained in this template can be adapted to the individual company layout as required by an individual notified body. As further feedback is received from Competent Authorities on the layout and contents of submitted NBOps this template may be updated to ensure efficient communication of this regulatory information.



# Team-NB Position Paper

**NB Logo**

**NB Name and Address**

**NB Number**

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## Notified Body Opinion

Article 117 of the Medical Device Regulation (EU 2017/745)

Compliance of device(s) incorporated into an integral drug-device combination product

with Annex I (General Safety and Performance Requirements) Medical Device Regulation (EU 2017/745)

Administrative reference number (including version number):	
Reviewer name and position:	
NB authorisation (signature):	
Issue Date of Notified Body Opinion: (YYYY/MM/DD)	

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## 1. INTRODUCTION

This report documents a summary of the opinion of the Notified Body with respect to the conformity of the device part of the <medicinal product > to the relevant GSPRs in Annex I of the Medical Device Regulation. This report was written at the request of the manufacturer in accordance to Article 117 of the 2017/745 Regulation. The information contained in this report is confidential to the manufacturer and is to be supplied in full as part of a Marketing Authorization Application, for the aforementioned <medicinal product>.

Information on the Product Under Assessment	
Name of the medicinal product (invented / generic name)*	
Marketing authorisation applicant	Name and Address
Marketing authorisation procedure number (if available)	
Regulation	2017/745
Review type	<input type="checkbox"/> Initial Assessment <input type="checkbox"/> Variation Assessment
Device part: Applicable MDA / MDN / (single selection - mandatory)	Please select
Device part: Applicable MDS code(s)	
Reference and date of applicant's application	

\*One NBOp is generally expected for one presentation of medicinal product with integral device but the opinion may cover multiple strengths.

This report was created in consideration of the following text as outlined in Article 117 of Regulation (EU) 2017/745 on Medical Devices, [sic]... “Where, if the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements (GSPR) set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.”

## 1.1. Summary of Notified Body Opinion

The technical documentation for <medicinal product> was reviewed in accordance with Annex I of Regulation 2017/745. The assessment has been performed for the purpose of < *initial application / variation application* >.

The objectives of this assessment were found to have been met/ not met for the applicable GSPRs.

GSPR Chapter	Assessment	
The device conforms to the relevant <b>General Requirements</b> as outlined in <b>Chapter I</b> of Annex I of Regulation (EU) 2017/745	<input type="checkbox"/> Yes	<input type="checkbox"/> No
The device conforms to the relevant <b>Requirements regarding Design and Manufacture</b> as outlined in <b>Chapter II</b> of Annex I of Regulation (EU) 2017/745	<input type="checkbox"/> Yes	<input type="checkbox"/> No
The device conforms to the <b>relevant Requirements regarding the Information supplied with the Device</b> as outlined in <b>Chapter III</b> of Annex I of Regulation (EU) 2017/745	<input type="checkbox"/> Yes	<input type="checkbox"/> No

A detailed summary of this technical documentation assessment is presented in sections 2 – 3 of this report below.

Conformity to the relevant GSPRs has been assessed. Non-applicable GSPR have been identified and sufficiently justified. Conformity with the following GSPRs are not fully met and rationale for non-compliance is provided in section <XXX>.

The Notified Body retains the technical documentation submitted by the manufacturer and related correspondence.

## 2. GENERAL PRODUCT INFORMATION FOR THE MEDICINAL PRODUCT

Summary information to ensure mutual understanding of the product under assessment including a detailed description of product, pharmaceutical form(s) and strength(s), in particular the device component(s), indications, method of administration, intended use, active or non-active device, sterile or non-sterile, etc.

### 2.1. General Description:

#### A general description of the medicinal product(s) and the device part(s)

Brief description to allow understanding of the design & packaging, characteristics (microbiological, chemical, mechanical, biocompatibility, sterility), and where appropriate, performance of the device(s) sufficient to distinguish between variants.

*Attributes to be considered in the general description:*

- *Dosing interval / schedule*
- *User requirements*
- *In-use time*
- *Accessories included or required for use .*
- *Existing or novel device (is expert opinion required)*
- *Market history (device history, different variants, changes to device, sales & complaints)*
- *Special notes – if necessary Critical specifications*

Any changes made to the device during pivotal clinical trials should be described (changes, timelines) and the impact on relevant GSPRs discussed. It should be clear to the Competent Authority which version of the integral device has been reviewed in case there are other changes between issuing the opinion and submission of the MAA.

*Include picture / schematic of device(s) if applicable.*

#### Short Description of the manufacturing process of the device(s)

#### References to aspects which have not been covered during the assessment

- *Final Sterilization Steps*
- *Packaging*
- *Aseptic Filling*
- *Others*

### 2.2. Intended Purpose of Drug/Device Combination:

A description of the intended use and operation of the device(s) by considering the therapeutic context of the medicinal product.

Proposed therapeutic indication (s) / Key risks, e.g. therapeutic index, side effects / Relevant precautions or contra-indications.

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Device specific clinical claims or risks

Target population(s)

Compatible devices – if applicable

### 3. ASSESSMENT OF THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPR)

Based on the documentation submitted by the applicant and the general information on the medicinal product stated within section 2 of this report, the **following conclusion can be made** for the device part under assessment (details on this evaluation are provided in section 3.1 of this report).

Evaluation criterion	Assessment Result	
All applicable General Safety and Performance Requirements are identified by the applicant. In circumstances where certain requirements within one applicable requirement are deemed not applicable for the device part under consideration, a rationale is provided by the applicant.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
For non-applicable General Safety and Performance Requirements justification has been provided to why they are not applicable to the device part under consideration.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>GSPRs listed as non-applicable:</p> <p>List the non-applicable GSPR numbers where justification has been accepted.</p>		
The methods used to demonstrate conformity with the requirements and the documented evidence for conformity with each of these methods is adequate	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Harmonised standards, common specifications, or other solutions employed by the manufacturer are suitable and applicable to fulfil the General Safety and Performance Requirements	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Comments on the assessment:</p> <p><i>Please insert a statement on the above assessment result– in case of “no” enter a justification for your decision and outline which GSPR are affected from this decision, please reference the respective section within the report. Enter a reference to the documentation supplied by the applicant which serves as evidence for the decision stated.</i></p> <p><i>Outline any additional comments on gaps and/or areas requiring specific consideration by the Competent Authorities</i></p>		

## 3.1. Solutions adopted to fulfil the GSPRs

Note this section is to provide a summary of the aspects reviewed per GSPR. Briefly describe the solutions adopted relevant to the GSPRs and the NB review, highlighting any areas of concern, even if the overall opinion is positive, for example biocompatibility can be demonstrated but ISO 10993-1 not followed.

### 3.1.1. Design and Manufacturing Information

<To cover GSPRs 1,4,7,8,11 to include process flow and locations packaging and sterility aspects  
Description of the manufacturing process

Aspects to be considered for the manufacturing process:

- Manufacturing and assembly flow chart and processes,
- Raw materials,
- suppliers and sub-contractors involved,
- In-coming and final controls,
- Release/final product specifications, manufacturing environment, manufacturing processes (incl. cleaning, sterilization...) and additives.

### 3.1.2. Design and Performance Validation

<e.g. human factors studies, GSPR 1,6,11. To include packaging and sterility aspects>

### 3.1.3. Benefit-Risk Analysis and Risk Management

<Short summary and conclusions to cover GSPR 1,2,3,4,5,8>

### 3.1.4. Biocompatibility

<GSPR 10 including CMR or endocrine disrupting substances>

### 3.1.5. Stability and Shelf Life

<GSPR 7>

### 3.1.6. Labelling and Leaflet

<to confirm the aspects of labelling that have been reviewed as part of the NB review for example output from risk assessment or instructions for use of the device part, GSPR 23>

<The headings below can be deleted if not relevant to the integral device part of the medicinal product in question>

### 3.1.7. Microbiology

<GSPR 11 To confirm microbiological state of components if claimed as sterile (sterilisation method and validation) e.g. as part of aseptic final fill process. Competent Authority are responsible for manufacturing steps once the medicinal substance is involved and the final microbiological state>

### 3.1.8. Tissues/cells of human or animal origin

<GSPR 13>



## Connection to other devices

<GSPR 14.1>

### 3.1.9. Measuring Function

<GSPR 15>

### 3.1.10. Electrical Safety, Software and EMC

<GSPR 17,18,19>

### 3.1.11. Protection from radiation, mechanical and thermal risks, and risks posed to the patient or user by devices supplying energy or substances

<GSPR 16, 20 and 21>

## 3.2. Recommendations to the Competent Authority

Summary of any concerns or elements for follow up. If full shelf life data, for example, has not been reviewed, this should be clearly highlighted to the Competent Authority together with recommendations for further action, for example would the NB need to review the final data before approval or not.

## 3.3. Standards

### Regulation, standards and guidance to which the Notified Body verifies compliance:

- MDR 2017/745 – Annex I,  
*List here any other Directive / standard / common specification / guidance document to which compliance is verified and verify if the provided list is complete and up to date*

## 3.4. Data Reviewed

### Reference and version number of the corresponding documentation assessed