# Team-NB Feedback on NBOps to date

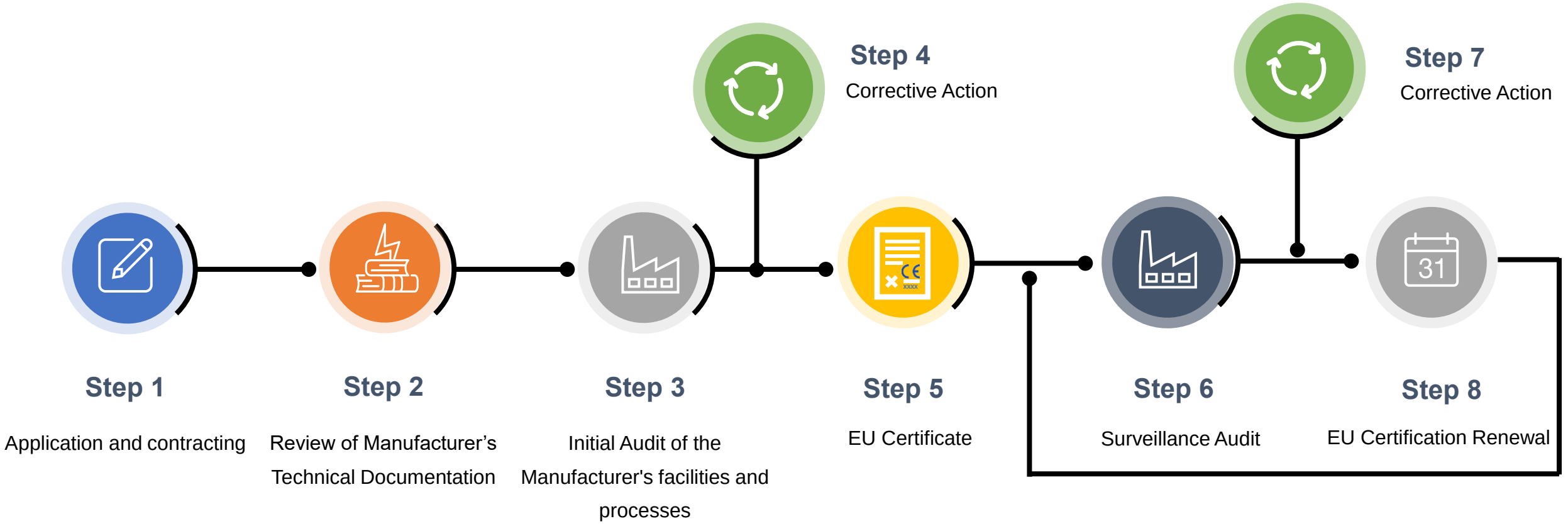
Julia Frese

Dr. Jonathan Sutch

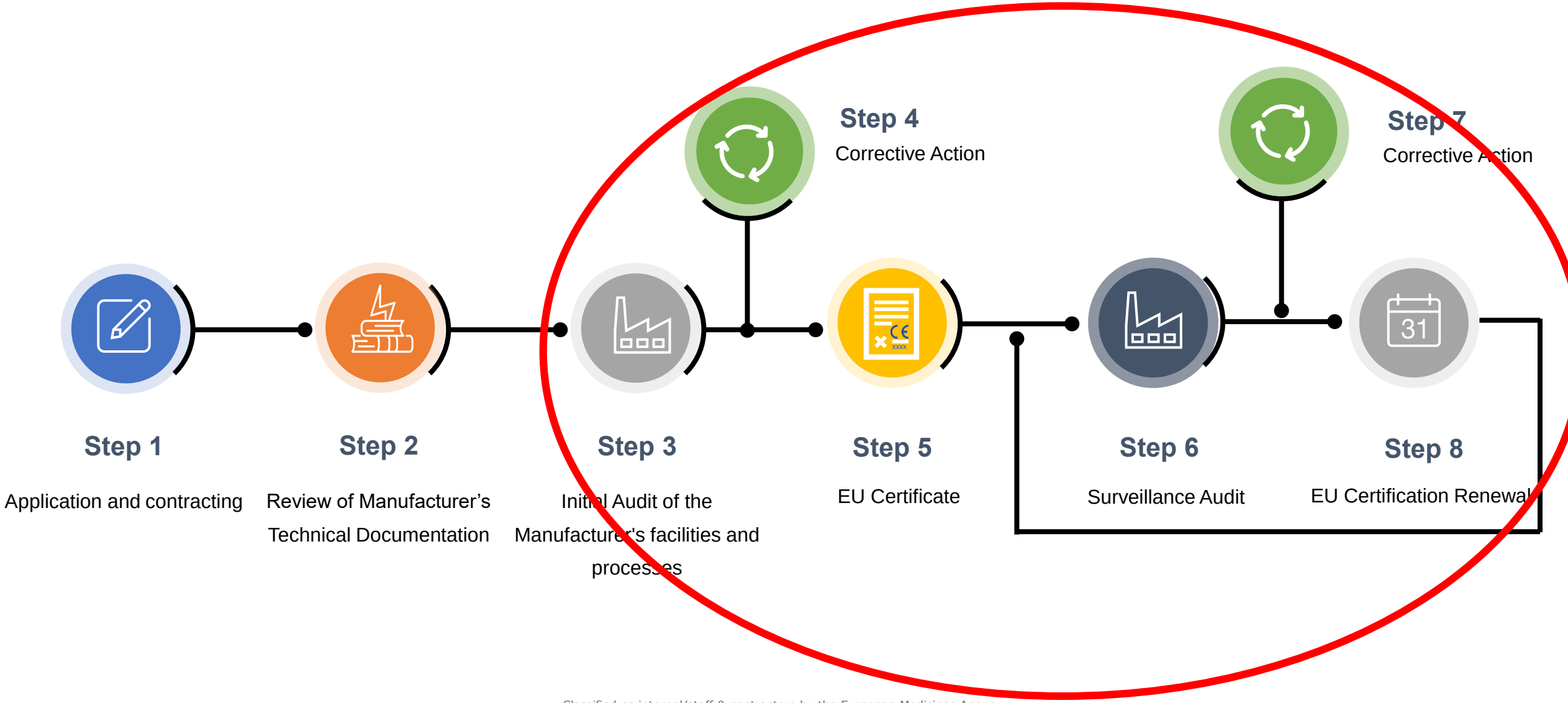
# Agenda

1. **NB Conformity Assessment Experience**
2. **Documentation Requirements and Learning Points**
3. **Review Experience – FAQ**
4. **Notified Body Opinion Report (NBOp)**
5. **Challenges for Notified Bodies**

# Process of EU Certification for Medical Devices



# Process of EU Certification for Medical Devices



# Requirements on Article 117 documentation

| Editor : Team-NB | Adoption date : 01/04/2020 | Version 1 |
|---|---|---|

**Team-NB Position Paper**

**on Documentation Requirements for Drug Device Combination Products**

**Falling in the Scope of Article 117 of MDR 2017/745.**

## Annex II

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

(a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

(b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards, CS or other solutions applied; and

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

https://www.team-nb.org/wp-content/uploads/2020/04/Team-NB_Position-Paper_on-Documentation-Requirements-Article117-V1.pdf

# Documentation Learning Points

01

**GSPR Checklist**

Ideally in the format of a checklist

02

**TOP Level Summary Reports**

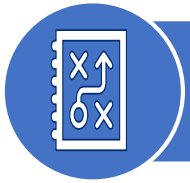
Detail from subcontractors and suppliers

Demonstrates MAH is in control of product

03

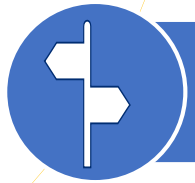
**Detailed Reports and Data**

Identification of Applicability and Justification



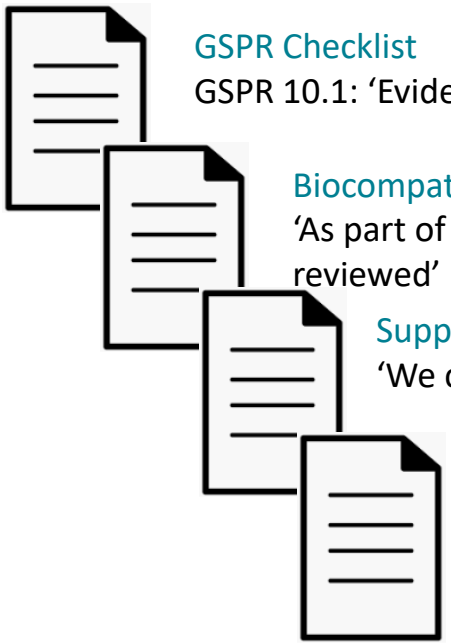
Methods used to demonstrate conformity

Harmonised standards / Common Specifications / Other guidance or applied state of the art solutions



Identification / Traceability of evidence

# Documentation Learning Points- Example



GSPR Checklist

GSPR 10.1: ‘Evidence is presented in Biocompatibility Summary Report’

Biocompatibility Summary Report

‘As part of an ISO 10993-1 approach supplier statements of conformity were reviewed’

Supplier statements of conformity

‘We confirm studies compliant with ISO 10993-1 have demonstrated conformity…’

ISO 10993-1 Assessment of Biocompatibility of component X

Data, Data, Data, Data, Discussion, Conclusion

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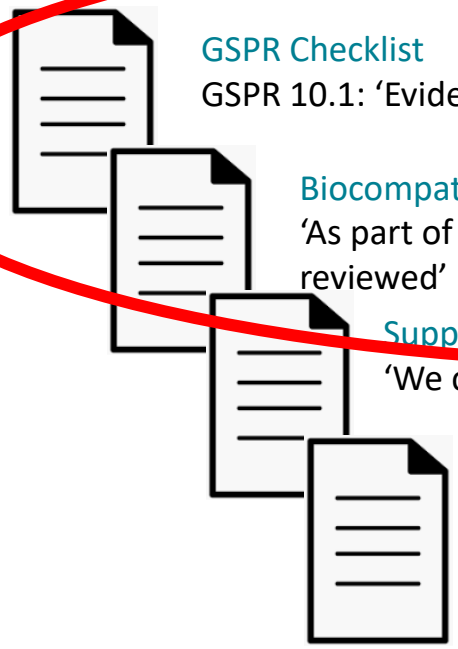

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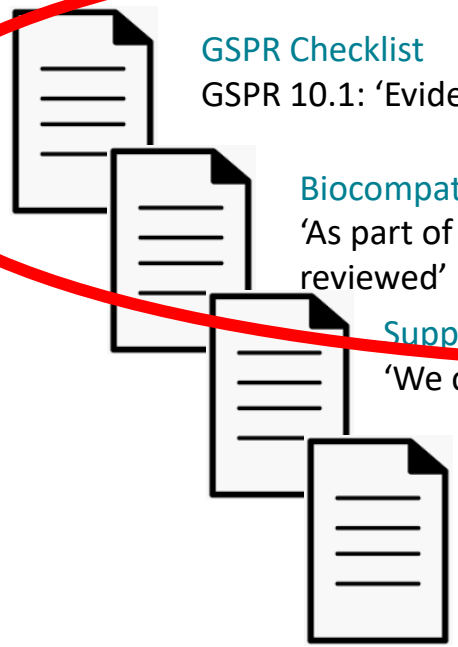

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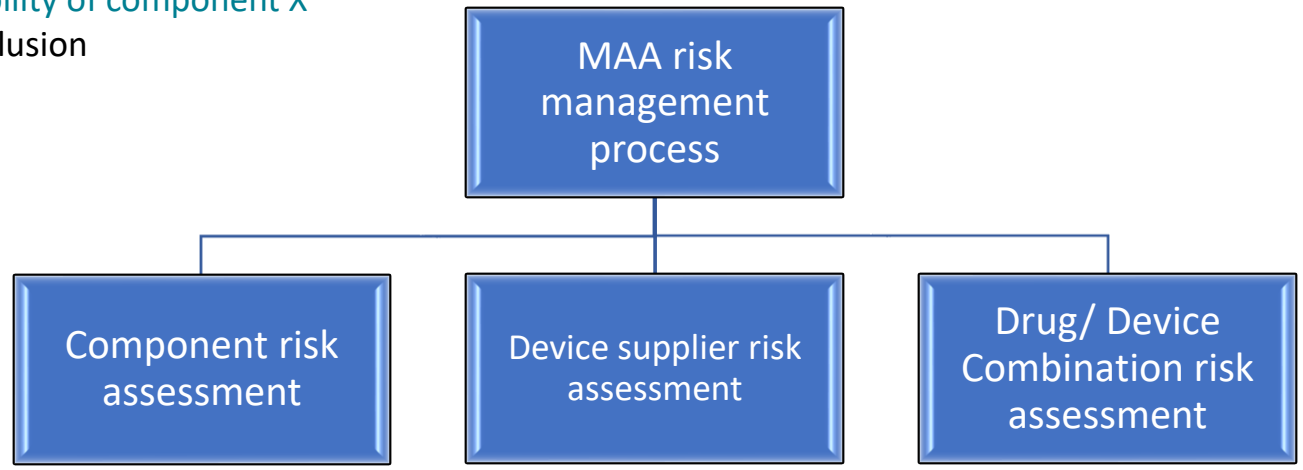


# Common Questions

**01**

## Clinical Use

Provide key risks, warnings and precautions related to the medicinal substance and the final device together with dose selection and adjustment criteria

**02**

## Overall Process

Please confirm 1. manufacturer's incoming checks and acceptance criteria
2. in-process checks and acceptance criteria 3. final inspection and test, release specifications and acceptance criteria 4. process validations.

**03**

## Administrative

Confirm MAH address vs. contracting entity
Confirm names and addresses of significant subcontractors or crucial suppliers

**04**

## Documentation

Provide the referenced reports related to design and manufacture, biocompatibility
Provide a copy User Requirement Specification for….
.

**05**

## Risk Management

Please provide a copy of the Risk Management Plan and Report for activities carried out at XXX

**06**

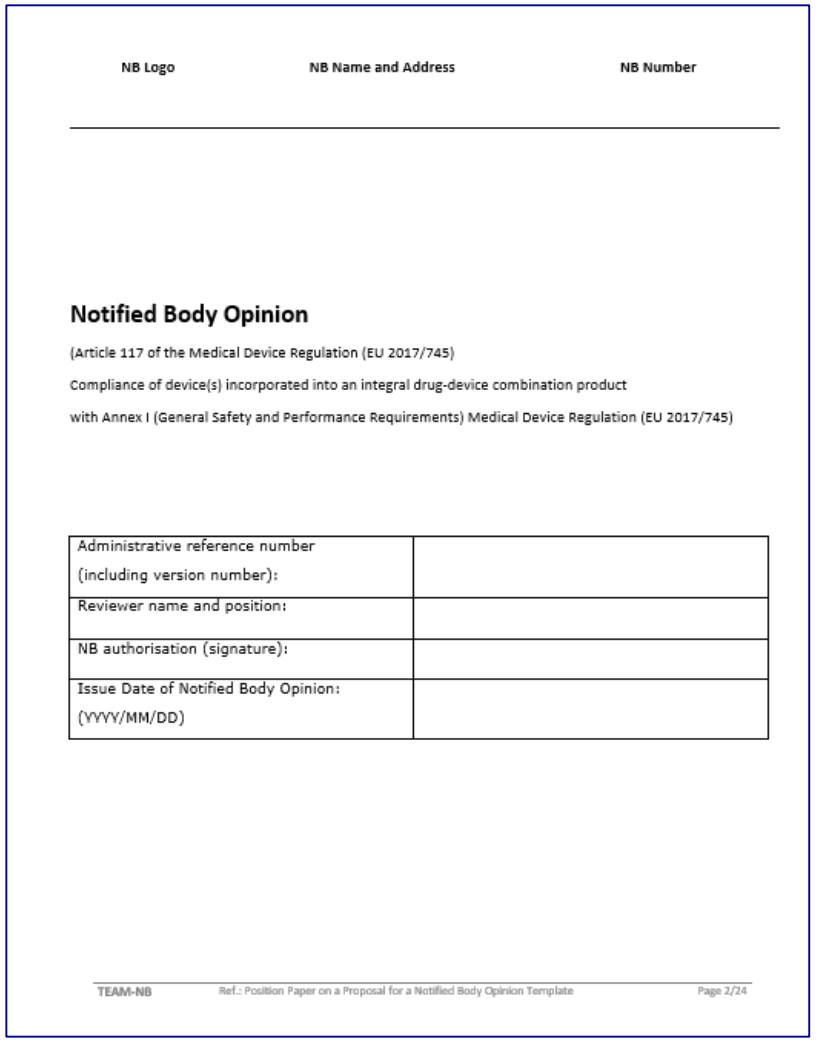
## TSE / CRM

Provide copies of the certificates, from those suppliers of components which contain materials of animal origin…

# Notified Body Opinion

Will take the form of a report

- Clear which version of the device has been evaluated
- Clear to Competent Authority what has been looked at
  - Sufficient detail to avoid duplication/ overlap
  - Sufficient detail to give confidence
- Any gaps clear to Competent Authority



NB Logo | NB Name and Address | NB Number

**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) | |

TEAM-NB Ref.: Position Paper on a Proposal for a Notified Body Opinion Template Page 2/24

# Notified Body Opinion- version 1

- Detailed review of GSPRs shared with Competent Authority
    - Partial compliance an option

| | | | |
|---|---|---|---|
| 18.8 | Design & manufacture – avoid unauthorized access | ☒**YES** ☐**NO** ☐**PARTIAL** | The product is provided in "tamper proof" packaging. IFU warns not to use the device if the seal is broken and to perform a visual inspection and not use the device if it looks damaged or if it has been dropped. |
| 19.1 | Active implantable devices – reduce risks as far as possible connected with use of energy sources, medical treatment, where maintenance and calibration are impossible | ☐**YES** ☐**NO** ☐**PARTIAL** ☒**N/A** | N/A – appropriate rationale given |

# NBOp- Future version

### 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* >. *In the case of variation assessment:* Previous results <*have been considered as documented in XXXX / have not been considered*>.

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 **General Requirements** as outlined in **Chapter I** of Annex I of Regulation (EU) 2017/745 | ☐ Yes | ☐ No |
| The device conforms to the relevant **Requirements regarding Design and Manufacture** as outlined in **Chapter II** of Annex I of Regulation (EU) 2017/745 | ☐ Yes | ☐ No |
| The device conforms to the **relevant Requirements regarding the Information supplied with the Device** as outlined in **Chapter III** of Annex I of Regulation (EU) 2017/745 | ☐ Yes | ☐ 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 rational for non-compliance is provided in section <*XXX*>.

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

### 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 10993-01:2019 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

#### 3.1.2. Design 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 medicinal product in question>

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

<GSPR 13>

#### 3.1.8. 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 an instruction that the NB needs to review or the Competent Authority don't need the NB to review the full data.

# Challenges

| | |
|---|---|
| **How will NBOp be used?** | ▪ Are the CAs looking for information in the NBOp or just that assessment is complete |
| **Responsibility where there is overlap** | ▪ Sterilisation- particularly components and re-sterilisation. EP specification.<br>▪ Shelf life |
| **What to do about incomplete data** | ▪ eg stability/ transport studies, draft SPC<br>▪ Does competent authorities accept the submission of the NBOp during the clock stop? |
| **What to handle non-fulfilled requirements?** | ▪ Missing evidence for an GSRP → Negative Opinion<br>▪ Follow up actions? Recommendations to the CA. |

# Conclusion

- Reviews have gone well to date
- Level of detail >>than self-certifying
  - Use supplier's knowledge
- Report work in progress
  - Simpler in future- but review behind it will remain the same
- Hope to publish template this year.