<Date>

Request for advice from the Expert Panels on the breakthrough device status pursuant to MDCG 2025-9 guidance[1]

[1] MDCG 2025-9 Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746

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Guidance text

Guidance text is in green italics. You may print a copy of this template with the drafting note, then delete them all in one go:

Click on Ctrl-Alt-Shift-S to view the "styles" window. Select "Drafting notes (Agency)" and click on the icon on the right, chose "Select all XXX instances", press the "Delete" key on the keyboard.

Do not change or delete the titles and the numbering style. (Add "Not applicable" if necessary)

Suggested font: Verdana 9.

Paragraph tab: alignment: left, outline level: body text, indentation: 0, spacing before: 0pt and after: 7pt; line spacing: at least, at: 14pt.

I – General Information

1. Administrative Information

1.1. Information on the requester

Name:

Position:

Email:

Phone:

1.2. Information on the manufacturer

Name of the company:

Address:

Country:

[For EU/EEA manufacturers]

SME status*: Yes ☐ /No ☐

*https://single-market-economy.ec.europa.eu/smes/sme-definition_en

1.3. Information on the authorised representative

[Mandatory for manufacturers outside of the EU/EEA and Turkey]

Name of the company:

Address:

Country:

1.4. Information on the notified body

[If already known]

Name of the notified body:

Address:

Country:

Notified body number:

2. Information on the device

2.1. Device name

Name:

2.2. Risk class

Class III	☐
Class IIb active device intended to administer and/or remove a medicinal product (Section 6.4 of Annex VIII - Rule 12)	☐

2.3. Risk class justification

[Please provide a justification for the risk class chosen, including the applicable classification rule.]

2.4. Type (European Medical Device Nomenclature -EMDN level 3)*

[Please indicate the EMDN type that applies to the device (multiple choices are possible)]

[*https://webgate.ec.europa.eu/dyna2/emdn/]

2.5. Clinical area

[Please indicate the relevant clinical area (multiple choices are possible)]

☐	Orthopaedics, traumatology, rehabilitation, rheumatology
☐	Circulatory system
☐	Neurology
☐	Respiratory system, anaesthesiology, intensive care
☐	Endocrinology and diabetes
☐	General and plastic surgery and dentistry
☐	Obstetrics and gynaecology, including reproductive medicine

☐	Gastroenterology and hepatology
☐	Nephrology and urology
☐	Ophthalmology
☐	Other: [ ]

2.6. Development history and regulatory status

[Please provide an up-to-date short overview of the device development. Describe the worldwide regulatory status of the device. Indicate if scientific advice has been previously requested from other regulatory authorities.]

3. Prioritisation criteria

[Please provide information on the criteria that apply to the device (multiple choices are possible).]

3.1. Device in the cardiovascular area

Yes ☐ ***/ No*** ☐

If Yes, please provide a justification:

[Outline the main features of the disease(s)/condition(s).]

3.2. Device intended for children

Yes ☐ ***/ No*** ☐

If Yes, please provide a justification:

[Describe the target population of patients.]

II – Application – Breakthrough device status criteria

[Please select the cell in the table that fits the device best. Please select only 1 cell. ***The following sections of this document (A-D) should provide the necessary justification for the selected category.****]*

Table 1: Illustration of Breakthrough criteria

Positive Clinical impact (see 4.2.3) **Novelty** (see 4.2.2)	**Non-significant positive clinical impact** *Does not contribute to clinically meaningful improvements in health outcomes compared with alternatives / SOTA*	**Significant positive clinical impact on patient health*** *Contributes to clinically meaningful improvements in health outcomes on an individual level*	**Significant positive clinical impact on public health*** *Contributes to clinically meaningful improvements in health outcomes on a population level*
Incremental / Sustaining Innovation *Low degree of novelty - Minor or iterative changes from alternative(s) / SOTA*	☐	☐	☐
Disruptive innovation *High degree of novelty - significantly differs from alternatives/ SOTA*	☐	☐	☐
Paradigm shift *High degree of novelty - Transformative innovation representing a fundamental change in a health area*	☐	☐	☐

** For a life-threatening or irreversibly debilitating disease or condition, see. 4.2.4.*

A. Description of the proposed breakthrough device

A1. Description of the device, principles of operation, mode of action

<Text>

A2. Proposed indication/ intended purpose

<Text>

B. Novelty of the proposed breakthrough device

[Please provide information on the novelty criteria that apply to the device. For guidance, the applicant can refer to section 4.2.1. of MDCG 2025-9.]

B1. Description of the novelty with respect to the device technology

<Text>

B2. Description of the novelty with respect to the related clinical procedure

<Text>

B3. Description of the novelty with respect to the application of the device in clinical practice

<Text>

C. Description of the targeted condition/population of the proposed breakthrough device

- **Name of condition/disease**
  <Text>
- **Aetiology**
  <Text>
- **Specific pathophysiological, histopathological, clinical characteristics**
  <Text>
- **Diagnosis and symptoms**
  <Text>
- **Justification of life-threatening or irreversibly debilitating character**
  <Text>

D. Significant positive clinical impact on patient or public health

D1. Details of the current state of the art and any existing alternative diagnosis, prevention or treatment methods

<Text>

D2. Justification as to why the existing methods are insufficient (where relevant)

<Text>

D3. Justification of the expected significant positive clinical impact on patient or public health compared to available alternatives and the state of the art

<Text>

D4. Justification of the fulfilment of an unmet medical need, where there is an absence or insufficiency of available alternative options for that purpose

<Text>

A comprehensive description of the current state of the art and alternative therapies (if any, including the relative availability of alternatives) should be provided in this section (D1). For guidance on describing the available alternatives and state of the art, the applicant can refer to section 4.2.4 of MDCG 2025-9.

The applicant should justify why the existing methods are insufficient (D2). Additionally, the applicant should justify why the device would provide an expected significant clinical impact on patient or public health compared to available alternatives or state of the art for the treatment, diagnosis or prevention of the disease/condition (D3), and/or why the device fulfils an unmet clinical need (D4). For the justification of the expected clinical impact, the applicant can refer to section 4.2.2 of MDCG 2025-9.

E. References

For all sections of this document, the manufacturer should provide references to support the claims on the breakthrough status of the device. Published authoritative references (for example, from peer-reviewed medical literature) are preferred where available.

III - List of Abbreviations

[Please provide a list of abbreviations used in this document, if applicable]