



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pilot Scientific Advice - Medical Device Expert Panels

Letter of Interest template for online application

Please do not submit this form

This document is for information only and to be used as a guidance for applicants in the preparation for the online submission of the letter of interest to be considered for the pilot scientific advice for the expert panels.

1. Applicant's Administrative Information

Name of the company: []

Address: []

Email: []

Phone: []

European Economic Area country:

SME status*: Yes/No

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



2. Device Information

Name of the device: []

Risk class

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

Risk class justification:

[Justify the risk class chosen, including the applicable classification rule.]

Type (European Medical Device Nomenclature -EMDN* level 3): [letter ## ##]

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

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

Clinical area

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

<input type="checkbox"/>	Orthopaedics, traumatology, rehabilitation, rheumatology
<input type="checkbox"/>	Circulatory system
<input type="checkbox"/>	Neurology
<input type="checkbox"/>	Respiratory system, anaesthesiology, intensive care
<input type="checkbox"/>	Endocrinology and diabetes
<input type="checkbox"/>	General and plastic surgery and dentistry
<input type="checkbox"/>	Obstetrics and gynaecology, including reproductive medicine
<input type="checkbox"/>	Gastroenterology and hepatology

<input type="checkbox"/>	Nephrology and urology
<input type="checkbox"/>	Ophthalmology
<input type="checkbox"/>	Other: []

Description of the device: [1000 characters]

[Provide a description of the device, including the mode of action, its intended purpose and target population]

Development history and regulatory status: [2000 characters]

[Provide a short overview of the product development. Describe the worldwide regulatory status of the product. Indicate if scientific advice has been previously requested from other regulatory authorities.]

3. Procedural Information

Prioritisation criteria

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

Device intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition (e.g., orphan devices and devices for paediatric use): Yes/ No

If Yes, provide a justification:

[Describe the target population of patients and provide an estimate of this population in the EU referring to relevant publications or other sources. Explicit the hypotheses made for this evaluation and provide a range of possible values reflecting the uncertainty around the estimation.]

Device for unmet medical needs: Yes/ No

If Yes, provide a justification:

[Devices for unmet medical needs are defined as devices for medical conditions that are life-threatening or cause permanent impairment of a body function and for which current medical alternatives are insufficient or carry significant risks (see MEDDEV 2.7/1 rev.4, Appendix 8)

Outline the main features of the disease(s)/condition(s) and the current standard medical treatments or diagnosis, referring to relevant publications or other sources.]

Novel device with a possible major clinical or health impact: Yes/ No

If Yes, provide a justification:

[Provide an assessment of the novelty of the device and the expected clinical and/or health impacts resulting from that novelty. This assessment is expected to be based on the Commission guidance for the medical device expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure.]

[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807\(01\)&rid=5](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&rid=5)