

CEN Reference:

BT N 18840

**Draft BT C242/2025**

CENELEC Reference:

BT182/DG18487/DV

## Simultaneous circulation to CEN and CENELEC TECHNICAL BOARDS

**BT by correspondence**

**CENELEC Agenda item:**

5.1.8

**For decision – IR2 Clause 6.2.3**

**Issue date:**

2025-12-03

**Deadline:**

**2026-02-24**

### SUBJECT

**New CEN-CLC/JTC on ‘Brain-computer Interfaces’**

### BACKGROUND

On 2025-11-10, DKE submitted a proposal to CCMC for the creation of a new Joint Technical Committee (JTC) in the field of Brain-computer Interfaces (BCIs) (see Annex 1).

The proposed JTC would be responsible for standardization in the area of Brain-Computer Interfaces (BCIs), including:

- foundational definitions,
- reference architectures,
- interoperability protocols,
- safety requirements,
- ethical design principles,
- technical specifications to ensure conformity

The proposed new JTC would identify/develop specific technical standards related to BCIs, a rapidly emerging family of technologies with applications in healthcare, assistive devices, human–computer interaction, education, and security.

ISO/IEC JTC 1/SC 43 ‘Brain-computer interfaces’ addresses global standardisation on BCIs. The establishment of a dedicated European committee would ensure that this work is fully aligned with EU-specific ethical, legal, and social requirements, maintains consistency with EU legislation such as the MDR, GDPR, and the AI Act, fosters innovation within the EU, and reinforces European engagement in international standardisation activities. The committee will therefore complement the work of ISO/IEC JTC 1/SC 43 by contextualising international developments within EU frameworks, with coordinated engagement across the relevant CEN, CENELEC, ISO, and IEC bodies to prevent overlap.

Furthermore, the new JTC will focus on developing standardized terminology and taxonomy for BCIs, as well as technical specifications addressing safety, data protection, and informed

consent. In addition, it will work on interoperability frameworks to support multi-sector BCI integration, together with guidelines for conformity assessment and testing.

A proposal for the initial work programme of the new CEN-CLC/JTC is also presented in Annex 1.

By BT 006/2020 and D164/004, CEN and CENELEC BTs respectively decided that the following criteria are to be met for creation a CEN-CLC/JTC:

- 12-week consultation by correspondence;
- Vote according to IR2, clause 6.2.3;
- At least 5 countries committed to participate.

Consequently, **Members are requested to state explicitly whether they are committed to participate in the work:**

- in CEN by means of the commenting field provided in the BT-balloting tool;
- in CENELEC by uploading a reply on the Collaboration Platform.

#### CEN

CEN/BT is asked to approve the creation of a new CEN-CLC/JTC following the provisions of IR2 clause 6.2.3 (non-mandated work, weighted).

*Note: Possible votes are 'Agrees', 'Disagrees with comments' and 'Abstains'. Any vote indicating 'Deferring decision' will be counted as 'Disagrees with comments'.*

#### CENELEC

CLC/BT is asked to approve the creation of a new CEN-CLC/JTC following the provisions of IR2 clause 6.2.3 (non-mandated work, weighted).

*Note: Possible votes are 'Agrees', 'Disagrees with comments' and 'Abstains'. In line with D150/065, at the end of the BT consultation, 'no reply' is considered as 'positive vote' and any disagreement, considered as 'negative vote', should be accompanied by a comment.*

#### PROPOSAL(S)

BT,

- having noted the proposal for a new field of technical activity submitted by DKE as included in Annex 1;
- considering that Members of the following countries have expressed their commitment to participate: <countries>;
- decided, in line with IR2 clause 6.2.3, to create a new CEN-CLC/JTC xxx 'Brain-computer Interfaces' with the following preliminary scope:

*'Standardisation in the area of Brain-Computer Interfaces (BCIs), including:*

- *foundational definitions,*
- *reference architectures,*
- *interoperability protocols,*
- *safety requirements,*

- *ethical design principles,*
  - *technical specifications to ensure conformity.'*
- allocated the secretariat of CEN-CLC/JTC xxx 'Brain-computer Interfaces' to DKE;
- asked the new CEN-CLC/JTC to submit its final title and scope for BT approval following its first meeting.

2025-11-25 – CPE



## PROPOSAL for a NEW FIELD OF TECHNICAL ACTIVITY

Date of circulation

CEN/TC / SC N .....

(where appropriate)

Secretariat

CENELEC/TC / SC (Sec) .....

(where appropriate)

Type of technical body  
proposed (TC / SC / BTTF)

CEN-CLC JTC

**IMPORTANT NOTE: Incomplete proposals risk rejection or referral to originator.**☒ The proposer has considered the guidance given in Annexes 1 and 2 during the preparation**Proposal** (to be completed by the proposer)**Title of the proposed new subject**

(The title shall indicate clearly and unambiguously, yet concisely, the new field of technical activity which the proposal is intended to cover.)

Brain-computer Interfaces

**Scope statement of the proposed new subject**

(The scope shall precisely define the limits of the new field of technical activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)

Development of standards related to Brain-Computer Interfaces (BCIs), including foundational definitions, reference architectures, interoperability protocols, safety requirements, ethical design principles, and technical specifications to ensure conformance

**Purpose and justification for the proposal.**

BCIs are rapidly emerging technologies with applications in healthcare, assistive devices, human-computer interaction, education, and security. While ISO/IEC JTC 1/SC 43 is addressing global BCI standardization, a European committee is needed to align these efforts with EU-specific ethical, legal, and social requirements, ensure consistency with EU legislation (e.g., MDR, GDPR, AI Act), support European innovation, and enhance participation in international standardization.

Is the proposed new subject actively, or probably, in support of European legislation or established public policy?

☒ Yes ☐ No

If Yes, indicate if the proposal is

- in relation to EC mandate(s): .....(which one(s))
- in relation to EC Directive(s)/Regulation(s): .....(which one(s))
- in relation to other legislation or established public policy: .....(give details)

#### Proposed initial programme of work

The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall therefore show the relationship between the subject proposed.

Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, terminology, characteristics, other requirements, data to be supplied, test methods, performance requirements, etc.). Supplementary justification may be combined with particular items in the programme of work.

The proposed programme of work shall also suggest priorities, target dates and the most appropriate type of deliverable (e.g. EN, TS) for each item

Standard terminology and taxonomy for BCIs (TS) Technical specifications on safety, data protection, and informed consent (EN/TS) Interoperability frameworks for multi-sector BCI integration (TS) Guidelines for conformity assessment and testing (TR/EN)

#### A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CEN, CENELEC, ISO and IEC deliverables.

The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization, or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

The committee complements ISO/IEC JTC 1/SC 43 by contextualizing international work within EU frameworks. Coordination with existing CEN, CENELEC, ISO, and IEC bodies will be established to avoid overlap.

#### A listing of relevant existing documents at the international, regional and national levels.

Any known relevant documents (such as standards and regulations) shall be listed, regardless of their source, and should be accompanied by an indication of their significance.

ISO/IEC JTC 1/SC 43 Strategic Business Plan MDR (Regulation (EU) 2017/745) GDPR (Regulation (EU) 2016/679) AI Act (proposed) León Declaration on Neurotechnology

#### Known patented items

☐ Yes ☒ No If "Yes", see CEN-CENELEC Guide 8 and provide full information in an annex

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) in particular those who are immediately affected from the proposal (see Annexes 1 and 2) and how they will each benefit from or be impacted by the proposed deliverable(s)

SMEs and large industry (enhanced innovation and clarity in conformity) Medical sector (safer integration of BCIs) Research institutions (alignment with ethical and legal standards) Consumers and civil society (greater protection and trust) Certificat

<b>Liaisons:</b> <b>A listing of relevant external European or international organizations or internal parties (other CEN, CENELEC, ETSI, ISO and/or IEC committees) to which a liaison should be established (in the case of ISO and IEC committees via the Vienna or Frankfurt Agreements).</b>	<b>Joint/parallel work:</b> <b>Possible joint/parallel work with:</b> <input type="checkbox"/> CEN (please specify committee ID) <input checked="" type="checkbox"/> CENELEC (please specify committee ID) TC 62 <input checked="" type="checkbox"/> ISO (please specify committee ID) JTC1-SC43 <input checked="" type="checkbox"/> IEC (please specify committee ID) JTC1-SC43 <input type="checkbox"/> Other (please specify)
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**Name of the Proposer**  
(include contact details)

Christian Marian  
CENELEC BT Permanent Delegate

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**An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.**

DKE is willing to hold the secretariat of this CEN-CLC JTC.

*C. Marian*

**Signature of the proposer**

**Annex(es) are included with this proposal** (give details)



**yes**

### Informative Annex 1 "Principal categories of market needs"

- Consumer protection and welfare
- Environment
- Innovation
- Support to:
  - public policy
  - European legislation/regulation
- Market access/barriers to trade, i.e. enhancing the free movement of:
  - services
  - goods
  - people
- Interoperability
- Health/Safety
- Terminology

## **Informative Annex 2 "Principal categories of stakeholders"**

- Industry and commerce,
  - where particularly appropriate, to be identified separately as
    - Large enterprises (those employing 250 staff or more)
    - Small and medium sized enterprises (SME), (those employing 250 staff or fewer)
- Government
- Consumers
  - including those organizations representing interests of specific societal groups, e.g. people with disabilities or those needing other particular consideration)
- Labour
- Academic and research bodies
- Non-governmental organisations (NGO),
  - including organizations representing broad or specific environmental interests
- Standards application business (e.g. testing laboratories, certification bodies)

Sometimes it is valuable also identify the immediate affected stakeholders from industry and commerce in terms of their position in a product value chain, as follows:

- Supplier
- Manufacturer
- Intermediary (e.g. warehousing, transport, sales)
- Service provider
- User of the product or service
- Maintenance / disposal

NOTE: 'Immediately affected stakeholders' are considered to be those who, within the context of the proposal, would be in a position to implement the provisions of the intended standard(s) into their products, services or management practices.