CEN-CENELEC Strategic Advisory Group on Healthcare Standards

Terms of Reference – Rev 1

1. Full title

CEN-CENELEC Strategic Advisory Group on Healthcare Standards (CEN-CLC/SAG Healthcare)

2. Status & Mission

The group is a Strategic Advisory Group (SAG) as defined in the CEN-CENELEC Internal Regulations Part 2.

The mission of the SAG is to explore the need for European standardization on Healthcare Standards and recommend ways to address these needs.

The SAG does not develop standardization deliverables.

The SAG cannot create sub-groups.

3. Scope

The SAG supports CEN and CENELEC in exploring the need for European standardization on Healthcare Standards within CEN and CENELEC, and advises the CEN and CENELEC Technical Boards on how to tackle this subject. It ensures interaction among all relevant stakeholders interested in potential standardization on Healthcare Standards.

The existence of the SAG does not prevent a CEN and/or CENELEC Member to submit a proposal for a new field of activity on Healthcare Standards.

4. Tasks

The SAG has the responsibility for the following tasks:

- analyse the landscape regarding two key challenges in healthcare standardization: Circularity / Sustainability aspects, and Artificial Intelligence (AI) / Machine Learning Technologies;
- identify and give due consideration to any relevant specific issues linked to European legislation;
- consider strategic issues concerning standardization on healthcare standards, with a focus as given above;
- coordinate mapping exercises to address missing standards on Circularity / Sustainability aspects, and AI / Machine Learning Technologies, to identify European standardization needs and define best ways for CEN and CENELEC to meet them;
- raise awareness on Circularity / Sustainability aspects and AI / Machine Learning Technologies in healthcare standardization;
- provide reports to CEN and CENELEC Technical Boards, as defined under clause 9 ‘Reporting line and timeline’.

5. Secretariat & Chair

The secretariat of the SAG is provided by a CEN Member, as appointed by the CEN and CENELEC Technical Boards.

The Chair is nominated by the secretariat of the SAG and appointed by the CEN and CENELEC Technical Boards for the foreseen duration of the SAG.

6. Membership

Membership includes the following participants:

Members:

☒ Representatives appointed by NCs/NSBs

☒ Representatives of Partner organisations incl. Annex III representatives, i.e.

- MedTech Europe
- Small Business Standards (SBS)
- DIGITALEUROPE

☒ Representatives of the relevant Technical Bodies, i.e.

- CEN/TC 55 'Dentistry'
- CLC/TC 62 'Electrical equipment in medical practice'
- CEN/TC 102 'Sterilizers and associated equipment for processing of medical devices'
- CEN/TC 140 'In vitro diagnostic medical devices'
- CEN/TC 170 'Ophthalmic optics'
- CEN/TC 204 'Sterilization of medical devices'
- CEN/TC 205 'Non-active medical devices'
- CEN/TC 206 'Biological and clinical evaluation of medical devices'
- CEN/TC 215 'Respiratory and anaesthetic equipment'
- CEN/TC 216 'Chemical disinfectants and antiseptics'
- CEN/TC 239 'Rescue systems'
- CEN/TC 251 'Health Informatics'
- CEN/TC 285 'Non-active surgical implants'
- CEN/TC 293 'Assistive products and accessibility'
- CEN/TC 362 'Project Committee - Healthcare services - Quality management systems'
- CEN/TC 367 'Project Committee - Breath-alcohol testers'
- CEN/TC 467 'Climate Change'
- CEN-CLC/JTC 3 'Quality management and corresponding general aspects for medical devices'
- CEN-CLC/JTC 16 'Active Implantable Medical Devices'
- CEN-CLC/JTC 10 'Material efficiency aspects for products in scope of Ecodesign legislation'
- CEN-CLC/JTC 21 'Artificial Intelligence'

☒ Representatives from the CEN and CENELEC staff

Invited participants:

By agreement of the SAG, and subsequent approval by the Technical Board(s) of the **CEN and CENELEC**, additional participants may contribute to the work, for instance

relevant EC Directorates General and EFTA Secretariat, relevant European associations or research projects.

Registration:

Members and invited participants are registered through the same processes that are used for technical bodies by

- NSBs and NCs for their relevant representatives
- CCMC for other members and invited participants.

7. Working methods

As far as possible, the SAG works by correspondence. Meetings will be held as required, preferably online.

The SAG uses the electronic platform of CEN.

The SAG shall work by consensus. If consensus cannot be reached, the issue has to be brought to the attention of the Technical Boards.

8. Setting-up - Lifetime

The SAG was set up by the CEN and CENELEC Technical Boards on 1 January 2025.

It will automatically be disbanded upon completion of its task, at the latest on 31 December 2026.

9. Reporting line & timeline

The SAG will report to the CEN and CENELEC Technical Boards at least once a year or when a decision is expected from the Technical Boards. These reports shall highlight the progress made regarding the objective given by the CEN and CENELEC Technical Boards.

The SAG will provide its final report to Technical Boards by December 2026.

10. Revision of Terms of Reference

Any update to these Terms of Reference shall be approved by the CEN and CENELEC Technical Boards.