



PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY

PROPOSER:

SASO

DATE OF CIRCULATION:

2026-03-20

CLOSING DATE FOR VOTING:

2026-06-12

A proposal for a new field of technical activity shall be submitted to the Office of the CEO, which will process the proposal in accordance with [ISO/IEC Directives, Part 1, Clause 1.5](#).

Furthermore, a proposal will be considered as complete if every information field is complete and follows the guidelines for proposing and justifying a new field of activity given in the [ISO/IEC Directives, Part 1, Annex C](#).

TITLE

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.2](#))

Wound dressings and compresses

SCOPE

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.3](#))

Standardization of particular aspects related to wound dressings and wound compresses, including but not limited to, design, safety and performance requirements and associated test methods for adhesiveness, absorption, waterproofness and skin-fitting. In addition to standardization of safety controls and terminologies for these products.

Excluded:

- aspects related to biological and clinical evaluation, covered by ISO/TC 194;
- quality management and corresponding general aspects, covered by ISO/TC 210.

PURPOSE AND JUSTIFICATION (Please use the field immediately below or attach an annex.)

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.13](#))

Ensure safety and performance of wound dressing and wound compresses products that are widely used in surgical, ambulance, therapeutic and home healthcare settings which necessitates thorough evaluations of such products using standardized tests that are relevant to clinical practice and real world wound care scenarios, and which provide measurable performance metrics. There is wide global relevance associated with common and massy manufacturing and supplying of wound dressings and compresses, and supported by existence of special classification of such products in ISO under the ICS (11.120.20) but there is no TC or even standards that address requirements of these products.

PROPOSED INITIAL PROGRAMME OF WORK (Please use the field immediately below or attach an annex)

Please see the [ISO/IEC Directives, Part 1, Annex C.4.4 and C-4.5](#))

For each item, the initial work programme shall define the deliverable type and target dates. The initial work programme shall also assign priorities to the different items.

- 1- Standardisation of the safety and performance characteristics of wound dressing and wound compresses products – International Standards (IS) and Technical Specifications (TS) – HIGH PRIORITY.
- 2- Standardisation of the safe use of wound dressing and wound compresses products – International Standards (IS) and Technical Reports (TR) – MEDIUM PRIORITY.
- 3- Standardisation of the terminology related to wound dressing and wound compresses products – International Standards (IS) and Technical Report (TR) – LOW PRIORITY.

RELATION OF THE PROPOSAL TO EXISTING INTERNATIONAL STANDARDS AND ON-GOING STANDARDIZATION WORK

- The proposer has checked whether the proposed scope of the new committee overlaps with the scope of any existing ISO or IEC committee or JTC1 sub-committee
- If an overlap or the potential for overlap is identified, the affected committee has been informed and an agreement has been reached between proposer and committee on
 - i. modification/restriction of the scope of the proposal to avoid overlapping,
 - ii. potential modification/restriction of the scope of the existing committee to avoid overlapping.
- If agreement with the existing committee has not been reached, please explain why the proposal should be approved.

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- Have proposals on this subject been submitted into an existing committee and rejected? If so, what were the reasons for rejection?

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LISTING OF RELEVANT DOCUMENTS (SUCH AS STANDARDS AND REGULATIONS) AT INTERNATIONAL, REGIONAL AND NATIONAL LEVEL

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.6](#))

- 1- Saudi Standard - SFDA.MD 7002:2023 “Absorbent Medical Cotton Wool – Requirements”
- 2- Saudi Standard - SFDA.MD 7003:2023 “Absorbent Medical Cotton Wool – Test Methods
- 3- European Standard – EN 14079:2003 “Non-active medical devices – Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze”
- 4- European Standard – EN 17854:2024 “Antimicrobial wound dressings – Requirements and test method”

LISTING OF RELEVANT COUNTRIES WHERE THE SUBJECT OF THE PROPOSAL IS IMPORTANT TO THEIR NATIONAL COMMERCIAL INTERESTS

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.8](#))

Australia, Canada, China, France, Germany, Japan, India, Ireland, Korea, UK, USA and other countries.

LISTING OF RELEVANT EXTERNAL INTERNATIONAL ORGANIZATIONS OR INTERNAL PARTIES (OTHER THAN ISO AND/OR IEC COMMITTEES) TO BE ENGAGED AS LIASONS IN THIS WORK

(Please see the [ISO/IEC Directives, Part 1, Clause C.4.9](#))

CEN/TC 205 – Non-active medical devices

IDENTIFICATION AND DESCRIPTION OF RELEVANT AFFECTED STAKEHOLDER CATEGORIES

(Please see [ISO Connect](#))

	Benefits/Impacts/Examples
Industry and commerce – large industry	Produce and supply safe and effective wound dressing and compresses
Industry and commerce – SMEs	Produce and supply safe and effective wound dressing and compresses
Government	Ensure safe and effective use of wound dressing and compresses
Consumers	Use wound dressing and compresses safely
Labour	Click or tap here to enter text.
Academic and research bodies	Conduct researches and studies based on wound dressings and compresses standards
Standards application businesses	Evaluate conformity to wound dressings and compresses standards
Non-governmental organizations	Click or tap here to enter text.
Other (please specify)	Click or tap here to enter text.

EXPRESSION OF LEADERSHIP COMMITMENT FROM THE PROPOSER

(Please see the [ISO/IEC Directives, Part 1, Annex C, Clause C.4.12](#))

If the proposal is approved, SASO is willing to undertake the roles of the leadership and secretariat.

- The proposer confirms that this proposal has been drafted in compliance with iso/iec directives, part 1, annex c**

SIGNATURE OF THE PROPOSER

OSAMAH MOHAMMAD N ALBARIKAN

COMMENTS OF THE ISO CENTRAL OFFICE (IF ANY)

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