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Chemical Characterisation

Updates from ISO/TC 194/WG 14

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Outline

- Chemical characterisation
  - Purpose, framework and challenges
- The WG 14 work programme
  - Current documents in development
  - Timelines and next steps

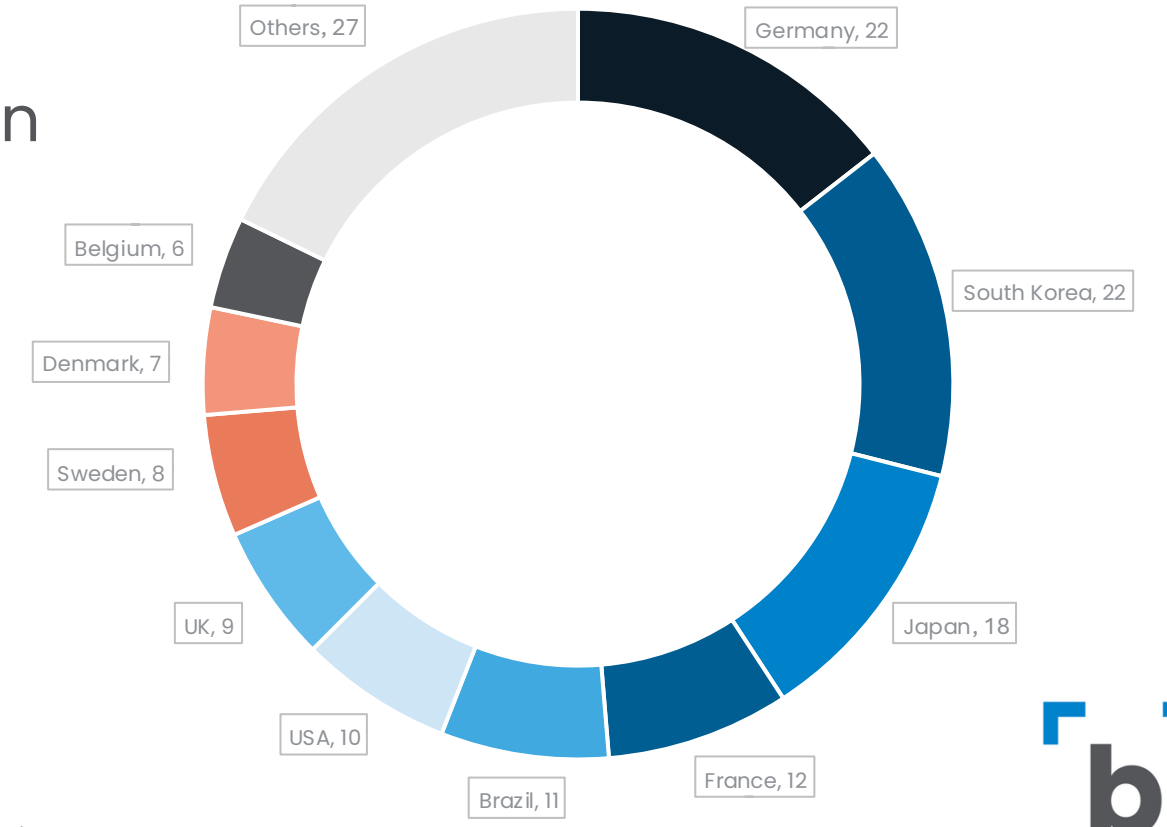
Disclaimer

- All opinions are my own and not those or other WG14 experts, and do not constitute official bibra or ISO positions
- ISO rules limit what I can share on the specific documents in development

About WG 14

About WG14

- ISO/TC 194: Biological and clinical evaluation of medical devices
  - WG 14: Material characterisation
- Currently 152 experts from 22 countries



About chemical characterisation

The purpose

- To understand the composition of a device and its materials
- But why..?
  - To enable/assist biological evaluation and TRA
  - To reduce or replace the need for new tests
  - To support equivalence arguments in device/material changes

The purpose

- Where can chemical characterisation data be used?
- Some standards are explicit in their acceptance
  - ISO 10993-3:2026 – **evaluation** of genotoxicity, carcinogenicity and reproductive/developmental toxicity
  - ISO 10993-17 – toxicological risk assessment
- In principle, a robust risk assessment based on chemical good characterisation data can be used for most (if not all) biological effects

The current framework

- ISO 10993-18 – defines the overall process
  - Searches for existing information
  - Novel testing – extractions
  - Provides identities and quantities of the constituents of a device
- ISO/TS 10993-19
  - Covers other (non-chemical) properties of material/device

The challenges

- Reproducibility
  - Long-standing concerns with inter-laboratory variability
- Quality
  - How can we establish criteria to ensure a consistent quality of data?
- Usefulness for biological evaluation and risk assessment
  - Need to remember that chemical characterisation is not an isolated task – the data needs to be useful

The work programme

The work programme

- A series of Technical Specifications were proposed to address these challenges and fill gaps in the existing framework
- Aiming to cover both technical and non-technical aspects of chemical characterisation

The work programme

Project	Stage	Title
ISO 10993-18	Published	Chemical characterization of medical device materials within a risk management process
ISO/TS 10993-19	Published	Physico-chemical, morphological and topographical characterization of materials
ISO/TS 11967	AWI	Guidance on commissioning scientifically robust chemical characterization testing in accordance with ISO 10993-18
ISO/TS 20324	CD	Generation of medical device extracts for chemical analysis to support toxicological risk assessment
ISO/TS 25364-1	DTS	Identification of organic extractables in non-targeted analysis (NTA)
ISO/TS 25364-2	CD	Quantification of medical device extractables and leachables using Non-Targeted Analysis (NTA)
ISO/TS 25364-3	CD	Instrumental and human requirements for evaluating organic medical device extractables and leachables via Non-Targeted Analysis (NTA)
ISO/TS 25364-4	AWI	Critical aspects of extract viability in extractables and leachables testing using non-targeted analysis (NTA)

ISO/TS 11967

- Long development
  - Origins in ISO meetings in Korea in 2017
  - Inter-laboratory round-robin for sample preparation
- Initially developed by WG 15
  - Transferred to WG 14 in 2024
  - Stripped back to only cover non-technical aspects

ISO/TS 11967

- Aim of current draft is to focus on general guidance for study sponsors
  - Avoiding overlap with the specific guidance on technical conduct of studies being presented in other documents
- Covers:
  - Selecting a laboratory
  - Establishing competence
  - Communication and responsibilities of the sponsor

ISO/TS 11967

- Approved as a Work Item by ballot, June 2026
- Several comments received
- Will be discussed in Tokyo next week
  - Aim to move to a formal Committee Draft for consultation in early 2027

ISO/TS 25364 Series

- Comprehensive guidance on conducting chemical characterisation studies
- Originally presented as a single document
  - Split into four parts

ISO/TS 25364-1

- Identification of organic extractables in non-target analyses
- General process recommendations supported by detailed informative technical annexes
  - Spectral matching
  - Assignment of identity confidence levels
  - Orthogonal techniques
  - Identity verification/corroboration

ISO/TS 25364-1

- Submitted as a Draft Technical Specification
  - Ballot ongoing – ends 23rd October
- Should be editorial comments only
  - Technical comments to be held over for a subsequent revision
- Hope to submit for publication by the end of the year

ISO/TS 25364-2

- Quantification of extractables
- Technical guidance with supporting annexes, covering:
  - Analytical evaluation threshold (AET)
  - Analytical uncertainty and the uncertainty factor (UF)
  - Strategies for quantification

ISO/TS 25364-2

- Submitted as a Committee Draft
  - Ballot complete, September 2026
- >400 Comments received, to be discussed and resolved next week in Tokyo

ISO/TS 25364-3

- Instrumentation and human requirements
- Officially at CD stage – inherited from original TS 25364 document
- Currently on hold – WG 14 decided to prioritise other documents
  - Intention to restart work during 2027

ISO/TS 20324 & ISO/TS 25364-4

- Two active projects in the workplan covering extracts:
  - ISO/TS 20324 – Generation of extracts
  - ISO/TS 25364-4 – Critical aspects of extract viability
- WG 14 decided to merge these into a single document:
  - *"Generation and viability assessment of extracts for chemical analysis to support toxicological risk assessment"*
- Currently being drafted – text to be discussed in Tokyo

ISO/TS 20324 & ISO/TS 25364-4

- Technical guidance on:
  - Solvents
  - Exhaustive vs. exaggerated vs. simulated use extractions
  - How to recognise and deal with compromised extracts
- A draft text has been circulated for discussion in Tokyo
  - Aim to progress to a formal Committee Draft ballot at the end of 2026/early 2027

Timelines

Project	Stage	Next steps	Timeline
ISO 10993-18	Published	Systematic review	2030
ISO/TS 10993-19	Published	Systematic review	2029
ISO/TS 11967	AWI	Development of a Committee Draft for ballot	Early 2027
ISO/TS 25364-1	DTS	Editorial changes and publication	End 2026
ISO/TS 25364-2	CD	Resolution of ballot comments	Tokyo, October 2026
ISO/TS 25364-3	CD	Development of a revised Committee Draft	2027
ISO/TS 25364-4	AWI	CD ballot on combined document	End 2026/Early 2027

Any questions?

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