Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

MAY NEWSLETTER 2025

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- Authorised Representative services across the globe
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- Translation services
- Local country listing

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OMC MEDICAL
Regulatory Services

REGULATORY SERVICES

Our mission is to support our clients in launching their products in various markets.

Who we are?

OMC Medical is primarily based in the UK with offices around the globe offering regulatory support to medical device manufacturers and distributors

- ✓ EU MDR and IVDR compliance
- ✓ Global language translation
- ✓ Global product registrations and Maintenance
- ✓ Product/Process compliance
- ✓ Labelling and Unique Device Identification
- ✓ Clinical evaluation and CRO Services
- ✓ Post-market surveillance
- ✓ Authorised Representative Services - EU, Swiss, UK and ROW.,
- ✓ Importer services - EU, Swiss
- ✓ Internal and External Auditing services
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EUROPEAN UNION (EU)

EMA Reviews Ipidacrine Medicines Over Safety and Efficacy Concerns | 23 May 2025

The European Medicines Agency (EMA) has begun a review of medicines containing ipidacrine, used in several EU countries to treat various neurological conditions in adults, including nerve inflammation, myasthenia gravis, memory disorders, and post-injury recovery.

This review, initiated at the request of the Irish medicines authority, follows concerns raised during an application for a generic version in four EEA countries. Questions were raised about the strength of the supporting data, which came largely from small or poorly designed studies—many lacking control groups or proper blinding.

Additional safety concerns have emerged, particularly regarding potential liver toxicity, as seen in a study showing elevated liver enzymes and supporting data from animal tests.

The EMA's Committee for Medicinal Products for Human Use (CHMP) will evaluate all available data to determine whether current marketing authorizations for ipidacrine products should be maintained, changed, suspended, or withdrawn across the EU.

EU Updates PMSV Requirements with New MIR Form Version 7.3.1 | 05 May 2025

The European Commission has released the latest version of the Manufacturer Incident Report (MIR) form—PDF 7.3.1—to support Post-Market Surveillance and Vigilance (PMSV) activities under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

This updated form is mandatory for manufacturers reporting serious incidents, Field Safety Corrective Actions (FSCAs), and follow-up updates involving medical devices and IVDs placed on the EU market, including those under transitional provisions from the previous Directives.

Key highlights of the MIR PDF 7.3.1 include:

- Improved alignment with EUDAMED data structure
- Enhanced data fields for software and IVD reporting
- Interactive, fillable PDF for structured submission

Until EUDAMED's vigilance module goes live, manufacturers must continue submitting the MIR directly to the relevant national competent authority.

This release underscores the EU's commitment to strengthening post-market oversight and ensuring patient safety through more consistent and transparent reporting.

UNITED KINGDOM (UK)

MHRA Launches Consultation on Draft Guideline for Using Real-World Data External Control Arms in Clinical Trials| 20 May 2025

The MHRA has released a draft guideline on using Real-World Data (RWD) to create External Control Arms (ECAs) in clinical trials. RWD ECAs use patient data collected outside traditional studies—such as from health records—to support the evaluation of new treatments.

Developed with input from the Commission on Human Medicines, the guideline outlines key considerations for sponsors planning trials that include RWD ECAs. While focused on RWD, the principles also apply to other external control sources.

A six-week public consultation is now open. Stakeholders are invited to review the draft and provide feedback, including line-by-line comments. The final guideline and a summary of responses will be published following the consultation.

MHRA Implements New GB MIR & FSCA Reporting Schemas | 16 May 2025

To align with the revised UK Medical Devices Regulations, the MHRA has introduced new GB-specific schemas for submitting Manufacturer Incident Reports (MIR) and Field Safety Corrective Actions (FSCA). These changes are part of the broader effort to improve post-market surveillance and ensure the continued safety and effectiveness of medical devices in Great Britain.

Effective 16 June 2025, the updated GB MIR and FSCA schemas will be available in the MORE (Manufacturer's Online Reporting Environment) portal.

Key changes include:

- GB-specific schema names – replacing EU references and aligning with UK regulatory frameworks.
- Removal of EUDAMED fields – including EUDAMED-assigned incident numbers and NCA identifiers.
- Inclusion of UK-specific data – such as UK Responsible Person details, UK Approved Body (UKAB) ID, and certificate numbers.
- Mandatory IMDRF coding – use of Annexes A–G for harmonised event classification.
- Expanded UDI fields – now including basic UDI-DI, unit of use UDI-DI, and issuing entity details.
- GMDN-only nomenclature – the schema now exclusively supports Global Medical Device Nomenclature codes.

These changes aim to improve data quality, consistency, and traceability in incident and FSCA reporting.

Transition Timeline

- 16 June 2025 – New schemas go live in the MORE production portal.
- 16 October 2025 – Final date to transition; older schemas will no longer be accepted beyond this point.
- Until then, manufacturers may continue using existing schemas if all new data fields are completed in free-text sections (e.g., general comments).

Manufacturers and UK Responsible Persons should:

- Review the new schema requirements
- Update internal reporting systems
- Train regulatory and quality teams accordingly

This change represents a significant step forward in aligning UK post-market surveillance with global standards while reinforcing the MHRA's commitment to patient safety. Make sure your processes are updated ahead of the transition deadline.

MHRA's MORE Portal: Strengthening Medical Device Safety Reporting | 16 May 2025

The MHRA's Manufacturer's Online Reporting Environment (MORE) is a digital platform for manufacturers to report adverse incidents and field safety actions related to medical devices used in Great Britain (GB) and Northern Ireland (NI). All incident reports must be submitted via MORE—other submission routes are not accepted.

New GB regulations, effective from 16 June 2025, enhance post-market surveillance by improving traceability and enabling faster risk response. To support this, MHRA has updated data requirements and submission formats for incident reporting.

In NI, EU MDR and IVDR rules apply, and manufacturers must continue using EU forms within MORE until the Eudamed Vigilance module is available. Despite EU alignment, the MHRA remains the reporting authority for NI.

MORE plays a key role in ensuring device safety by centralizing and standardizing incident reporting.

UNITED STATES OF AMERICA (USA)

FDA to Remove Ingestible Fluoride Products for Children | 13 May 2025

The FDA has announced plans to remove concentrated ingestible fluoride prescription products for children from the market. Unlike fluoride toothpaste or rinses, these products are swallowed and have never been FDA-approved.

Recent studies suggest ingesting fluoride may disrupt gut health and is linked to concerns such as thyroid issues, weight gain, and possibly reduced IQ—especially troubling in early childhood when the gut microbiome is still developing.

The FDA is conducting a safety review, with a decision expected by October 31.

Meanwhile, updated guidance on safe and effective dental hygiene practices for children will be issued, focusing on approaches that do not impact gut health.

This move reflects a shift toward prioritizing natural, non-invasive dental care and aligns with global trends to reduce systemic fluoride exposure.

TGA Updates GMP Clearance Guidance: New Inspection Pathway and Annex 16 Requirements| 21 May 2025

The Therapeutic Goods Administration (TGA) has issued updates to its GMP clearance guidance, reflecting recent international regulatory developments.

- **Health Canada Inspection Pathway Introduced**

Following a 2024 agreement with Health Canada, inspections conducted by Health Canada may now be used to support GMP clearance applications via the inspection reliance pathway. The relevant guidance documents and e-form instructions have been updated to reflect this addition.

- **Annex 16 Implementation**

With the adoption of Annex 16 – Authorised Person and Batch Release from the PIC/S Guide to GMP (effective June 2024, with the transition period ending September 2024), the TGA has updated its guidance to include the types of evidence that may be reviewed during GMP evaluations. There is currently no change to the upfront evidence requirements.

- **Clarification on Letters of Access (LoAs)**

The TGA continues to observe issues with the incorrect use of Letters of Access. The guidance now provides additional clarification to support the correct and effective use of LoAs in order to reduce delays and regulatory burden.

ANMAT Mandates QR Codes on Packaging of Synthetic Medicinal Products | 19 May 2025

ANMAT Provision No. 3294/2025 mandates QR codes with anti-fraud tech on the secondary packaging (and optionally primary) of all synthetic and semi-synthetic medicines. The code must link to the product leaflet and be easily scannable.

The rule takes effect one year from its enforcement date. QR codes will be issued by the National Institute of Medicines and required during new registrations and for existing marketed products.

Any leaflet updates must be reflected in the QR code. Placement must ensure visibility and readability. This move strengthens traceability and patient access to information.

ANMAT Lifts Restrictions on Non-Prescription Medicinal Products | 19 May 2025

ANMAT has announced that it will no longer intervene in the import of non-prescription medical products intended solely for personal use. As per Provision No. 2857/2025, this applies to products acquired by individuals for direct use without medical supervision.

The move aims to simplify procedures and improve access to medical products. However, resale or free distribution of these items remains prohibited.

A list of eligible products has been prepared by the National Institute of Medical Products and will be updated regularly. Importers assume full responsibility for proper use and any associated risks.

This change reflects ANMAT's commitment to improving regulatory efficiency while supporting patient autonomy.

BELGIUM

FAMHP Introduces Contact Form for Medicinal Product Queries | 27 May 2025

From 1 June 2025, the Federal Agency for Medicines and Health Products (FAMHP) will introduce a new mandatory contact form for submitting questions related to variations and renewals of medicinal products for human use. This form will replace the current email address previously used for such inquiries.

The new system is designed to streamline communications through partial automation and faster response times. Users will receive confirmation upon submitting the form, and are advised to consult the guidance on the FAMHP website to ensure all required information is provided.

The form covers a range of topics, including variation and renewal submissions, status updates, fee-related questions, document corrections, and sunset clause queries.

Processing times will vary based on the type of question, ranging from 5 to 30 working days.

BRAZIL

Anvisa Releases Draft Manual for UDI Medical Device System | 23 May 2025

Anvisa has released a draft version of the Manual for the Use of the Unique Identification System for Medical Devices (Siud), offering early guidance on Brazil's upcoming UDI (Unique Device Identification) database.

This initiative stems from RDC 591/2021, which mandates the development of a national UDI system aligned with international IMDRF standards to improve traceability and patient safety. The database is part of Anvisa's Strategic Plan 2024–2027 and will support registration and monitoring of medical devices across all risk classes.

The draft manual covers the system's completed features but excludes components still under development. The UDI database will only go live once the new regulation—currently under Public Consultation No. 1,313/2025—is finalized and enters into force.

Once effective, deadlines for mandatory UDI data submission will begin:

- Class IV devices: 3.5 years
- Class III devices: 4 years
- Class II devices: 5 years
- Class I devices: 6 years

This move marks a major step forward in aligning Brazil's regulatory system with global practices.

Anvisa Launches Targeted Consultation on Reusable and Single-Use Medical Device Regulations | 16 May 2025

Anvisa launched a targeted consultation aimed at the National Health Surveillance System (SNVS) to gather feedback on proposed regulations related to medical device classification and processing practices.

The proposals cover two key areas:

- Classification of medical devices as reusable or single-use
- Good practices for processing devices in healthcare settings and processing companies

This consultation is part of Anvisa's 2024/2025 Regulatory Agenda (Project 15.5) and aims to refine drafts before moving to public consultation. The process allows health surveillance agencies to contribute insights that will support the development of more robust and evidence-based regulations.

The consultation is open for 30 days and includes three main topics:

- Good practices in healthcare services
- Best practices in processing companies
- Validation protocols for medical device reprocessing
- Classification and regulatory pathways for single-use and reusable devices

Access the drafts and submit contributions here:

- Healthcare Services – SEI 3259104
- Processing Companies – SEI 3264670
- Validation Protocols – SEI 3264744
- Device Classification – RDC Proposal

Anvisa encourages active participation to strengthen national regulations and improve safety standards in medical device management.

TFVS Integration with Foreign Trade Portal: New Implementation Dates Announced | 09 May 2025

Anvisa has announced a revised schedule for the implementation of the Sanitary Surveillance Inspection Fee (TFVS) integrated with Brazil's Single Foreign Trade Portal. The update follows a temporary suspension in April 2025 to allow for system adjustments and protocol corrections, which were successfully validated between April 21 and May 2.

The TFVS will now be integrated with the Centralized Payment of Foreign Trade (PCCE) in a phased manner:

- May 12, 2025 – Import petitions for food
- May 26, 2025 – Cosmetics, sanitizers, standards, baby bottles, biological materials
- June 2, 2025 – Medicines and controlled substances
- June 9, 2025 – Medical devices

This phased rollout aims to improve processing efficiency and ensure smoother coordination across Brazil's trade and health surveillance systems.

SPAIN

AEMPS Launches AI Tool MeQA for Easier Access to Medicine Info | 13 May 2025

The Spanish Agency for Medicines (AEMPS) has introduced MeQA, an AI tool that answers questions about human medicines in everyday language using official drug leaflet data.

Aimed at improving public understanding of medicine use, dosage, and interactions, MeQA also has potential for future integration with electronic health records for personalized care.

This initiative reflects AEMPS's commitment to using technology to enhance public access to health information.

AEMPS and EMA Held Session on Enhancing Patient Role in EU Clinical Trials | 13 May 2025

the Spanish Agency for Medicines and Health Products (AEMPS) and the European Medicines Agency (EMA) hosted an online session titled "Clinical trials in the EU: placing the patient at the centre" to mark International Clinical Trial Day.

The session focused on EU and national initiatives to strengthen patient involvement in clinical research, particularly through the ACT EU (Acceleration of Clinical Trials in the EU) project. This initiative aims to reinforce the EU's position as a leader in high-quality, safe, and effective clinical trials and to better integrate clinical research into the healthcare system.

An interactive map within the Clinical Trials Information System (CTIS) was also presented to improve public access to real-time information on clinical trials across the EU. The session concluded with a discussion and Q&A with institutional representatives.

SOUTH AFRICA

SAHPRA Lists First Mpox Diagnostic Test Using WHO Reliance Pathway | 22 May 2025

The South African Health Products Regulatory Authority (SAHPRA) has approved its first in vitro diagnostic (IVD) test for mpox (monkeypox) through a reliance mechanism based on the World Health Organization's (WHO) Emergency Use Listing (EUL) and Prequalification (PQ) assessment. This marks a key milestone in improving global access to mpox testing.

The approved test, the Alinity m MPX assay developed by Abbott Molecular Inc. and licensed to Abbott Laboratories South Africa, enhances diagnostic capacity during mpox outbreaks by enabling rapid and accurate detection of the virus. SAHPRA highlighted the significance of using regulatory reliance mechanisms to expedite access.

Only molecular RT-PCR tests are currently considered for approval by SAHPRA, specifically those using nasal swabs. Both the Africa CDC and WHO have emphasized that no antigen rapid diagnostic tests (RDTs) have met the minimum required sensitivity (80%) for mpox testing in Africa. As a result, antigen and antibody rapid tests—including self-test kits—are not recommended.

For further details, SAHPRA's regulatory requirements are outlined in communication MD01-2024/25 v1, available on their official website.

EUROPEAN UNION (EU)

EU Proposes Revisions to Cosmetics Regulation to Align with Updated CMR Substance Classifications| 21 May 2025

On May 21, 2025, the EU submitted a draft regulation to the WTO to revise four ingredient lists under Regulation (EC) No 1223/2009 (Cosmetics Regulation). The proposal, open for public comment until July 20, 2025, aims to take effect on May 1, 2026. It follows the adoption of Delegated Regulation (EU) 2024/2564, which updated classifications for certain substances, including newly recognized CMR (carcinogenic, mutagenic, or toxic for reproduction) substances.

The draft seeks to ensure consistent enforcement of CMR-related bans while allowing the continued use of specific CMR substances proven safe.

EU SCCS Finalizes Opinions on Three Cosmetic Ingredients Concerning Children's Exposure| 06 May 2025

The EU Scientific Committee on Consumer Safety (SCCS) has issued its final safety opinions on three cosmetic ingredients — butylparaben, salicylic acid, and methyl salicylate — with a focus on use in children. The opinions, published on May 2, 2025, follow public consultation on the preliminary drafts released in January.

Ingredients	Use	SCCS Conclusion
Butylparaben (CAS No. 94-26-8)	Preservative in creams, lotions	Safe for children over 3 years; not confirmed safe for under 3, especially in nappy creams.
Salicylic Acid (CAS No. 69-72-7)	Exfoliant, anti-dandruff agent	Safe for children over 3 years; not safe in leave-on products for under 3.
Methyl Salicylate (CAS No. 119-36-8)	Fragrance, oral care flavoring	Safe for children 6+ in limited amounts; not safe for under 6s, especially in leave-on products.

These findings may lead to future updates to the EU Cosmetics Regulation. Manufacturers are urged to reassess formulations and labeling for child-appropriate use.

Thailand Imposes New Rules for Cosmetics Containing Titanium Dioxide | 08 May 2025

Thailand has introduced new regulations for cosmetics containing titanium dioxide (TiO_2), effective May 2025. The rules distinguish between nano and non-nano forms of the ingredient, with limits on concentrations in face powders and hair sprays to reduce inhalation risks. Products with titanium dioxide must also carry specific labels, particularly for those with particles smaller than 10 microns. Manufacturers are given until May 2025 to comply with the new guidelines, aimed at enhancing consumer safety and aligning with international standards.

Sri Lanka NMRA Issues Updated Cosmetic Registration Requirements Effective June 1, 2025 | 19 May 2025

On May 19, 2025, Sri Lanka's National Medicines Regulatory Authority (NMRA) published an updated checklist for cosmetic product registration, applicable from June 1, 2025.

The revised requirements outline specific documentation for both importers and local manufacturers. Importers must submit 11 documents, including an attested Free Sale Certificate, Certificate of Analysis with heavy metal testing, and proof of GMP or ISO 22716 compliance.

Local manufacturers are required to submit 8 core documents, such as a GMP certificate from NMRA, a Safety Data Sheet, and steroid-free declarations for applicable products. Additional documentation is needed if the brand owner differs from the manufacturer.

NMRA Introduces Single File Submission for Multi-Colour Cosmetic Products in Sri Lanka | 23 May 2025

Starting June 1, 2025, Sri Lanka's National Medicines Regulatory Authority (NMRA) will implement a Single File Submission policy for the registration and re-registration of cosmetic products with up to ten colour variants in the same product series.

Applicable to a wide range of colour cosmetics (e.g., lipstick, foundation, nail polish), this policy allows for one consolidated application, provided all product attributes except colour are identical. Although submissions are streamlined, the fee remains equal to the cost of ten separate applications.

The NMRA aims to improve efficiency in regulatory processes through this update.

Malaysia Digitizes Halal Certification with Launch of e-Cert System | 09 May 2025

Effective May 5, 2025, Malaysia's Department of Islamic Development (JAKIM) has implemented the electronic issuance of the Malaysian Halal Certification Certificate (SPHM) via the MYeHALAL system. This change supports the national Public Service Digitalization agenda by streamlining the certification process. All approvals granted on or after this date by JAKIM, State Islamic Religious Councils (MAIN), or State Departments (JAIN) will receive digital certificates, which applicants can print themselves.

Physical copies can still be requested officially, subject to fees outlined in the 2020 certification manual. The shift underscores JAKIM's efforts to modernize and improve service delivery.

BRAZIL

Second Edition of RDC 894/2024 Q&A Released to Support Cosmetovigilance Compliance | 13 May 2025

Anvisa has published the second edition of the "Questions and Answers about RDC 894/2024," a resource aimed at helping the cosmetic products sector understand and implement Good Cosmetovigilance Practices. This updated version includes six new Q&As developed in response to inquiries from industry stakeholders, highlighting the agency's commitment to transparency and regulatory clarity.

RDC 894/2024, which replaces RDC 332/2005, introduces more comprehensive guidelines for post-market surveillance of cosmetics, focusing on consumer safety and harmonized industry practices.

The Q&A document plays a key role in supporting businesses as they adapt to the new requirements. Its development reflects ongoing engagement between Anvisa and the regulated sector through associations and direct consultations. This collaborative approach helps ensure the regulation is practical and effective.

The updated document is available online, and Anvisa encourages continued participation from the sector, including the submission of further questions to enhance future editions.

SPAIN

Spain Launches Annual Campaign to Strengthen Cosmetic Product Safety| 21 May 2025

The Spanish Agency for Medicines and Health Products (AEMPS) has initiated a recurring annual campaign to verify the safety assessments of cosmetic products available on the Spanish market. This effort is part of the agency's ongoing market surveillance strategy.

The campaign emphasizes that cosmetic products must undergo a safety assessment before being placed on the market. The responsible company is obligated to conduct this evaluation and compile a corresponding safety report, which is included in the product information file, as outlined in Annex I of the Cosmetics Products Regulation.

AEMPS aims to underscore the critical role of safety assessments and related documentation in safeguarding public health. These measures provide assurance that cosmetic products are safe for consumer use.

This year, the campaign will focus on cosmetic product categories that have shown a rise or notable change in reports to the Spanish Cosmetovigilance System.

AEMPS Warns Against Misuse of Hyaluronidase in Aesthetic Treatments | 13 May 2025

The Spanish Agency for Medicines and Health Products (AEMPS) has issued a warning regarding the proper use of hyaluronidase, particularly in aesthetic treatments involving hyaluronic acid fillers. The agency highlights increasing incidents where hyaluronidase products marketed as cosmetics have been used incorrectly by injection, which is prohibited and poses serious health risks.

Hyaluronidase is available as both a cosmetic and a medicine. Cosmetic versions are only approved for topical use and must be clearly labeled with warnings such as "Topical use, do not inject." These products must not be administered through injection or similar invasive techniques. Medical-grade hyaluronidase for injection can only be obtained as a foreign medicine through a special request and must be administered by qualified healthcare professionals.

AEMPS has identified cases of misuse, including instances where cosmetic hyaluronidase was injected despite proper labeling, and where misleading marketing or training encouraged improper use. Such actions are considered professional malpractice and breach existing regulations.

To address these issues, AEMPS urges professionals and the public to distinguish clearly between cosmetic and medicinal forms of hyaluronidase, follow legal requirements, and ensure proper training for safe use.

Vietnam Increases Oversight on Cosmetics and Sunscreens Amid Surge in Counterfeit Products | 21 May 2025

In May 2025, Vietnam's Drug Administration (DAV) issued urgent directives to local health departments to step up inspections and enforcement against counterfeit, smuggled, and substandard cosmetics—especially sunscreens. The move follows increased reports of mislabeled and unregulated products, particularly sold online.

Authorities are instructed to inspect manufacturers, test products, monitor online sales, and penalize violations. Special focus is placed on sunscreens, requiring review of SPF claims, product labeling, and testing. Cosmetic companies must ensure compliance with regulations and be prepared for audits.
These actions align with broader government efforts to combat fake and unsafe health-related products.

CANADA

Health Canada Proposes Updates to Cosmetic Ingredient Hotlist | 21 May 2025

Health Canada has announced proposed amendments to its Cosmetic Ingredient Hotlist ahead of a formal consultation process. These updates include:

- **New Restrictions:**
  - Basic Violet 4, Basic Blue 7, and PHMB may face use limitations due to health risks identified under the Chemicals Management Plan (CMP).

- **Revised Entries:**
  - Symphytum spp. may lose its exception due to toxic alkaloids.
  - Brucine could be reclassified as prohibited.
  - Imperatorin may be removed as a separate entry and covered under furocoumarins.
  - Furocoumarins: Clarification that only trace amounts from natural extracts are allowed in leave-on products.

- **Other Changes:**
  - Minor corrections, added synonyms, and CAS numbers.

- **CMP Reviews:**
  - Additional substances, such as parabens and salicylates, are under review for potential future updates.

This notice is informational only; Health Canada is not accepting comments at this stage. Immediate regulatory action may be taken if a serious risk is identified, even before formal hotlist updates are finalized.

About the Hotlist:
The Cosmetic Ingredient Hotlist serves as a tool for stakeholders to identify ingredients that may contravene Canada's Food and Drugs Act or Cosmetic Regulations, including those with no functional purpose in cosmetics.

List of ISO standards updated in May 2025

- ISO 10993 4:2017/Amd 1:2025 - Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood — Amendment 1

- ISO 19223-2:2025 - Lung ventilators and related equipment — Vocabulary and semantics — Part 2: High frequency and jet ventilation

- ISO 7176-21:2025 - Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

- ISO 11137-1:2025 - Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a steriliz