Newsletter

REGULATORY BRAINBOX

OMC MEDICAL
Regulatory Services

Medical Devices Regulatory Consultancy

JANUARY NEWSLETTER 2025

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- Authorised Representative services across the globe
- EU MDR/FDA/ROW
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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
- ✓ Regulatory Staffing
- ✓ Regulatory Training

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EUROPEAN UNION (EU)

EU Releases New MDCG Documents | January 2025

The European Commission has released the following guidelines in January

Title	Overview
Preliminary assessment review (PAR) form template (MDR) ***Annex to Application Form & PAR Template MDR (List of documents)*** MDCG 2024-7 rev.1 MDCG 2021-15/MDCG 2024-7 Annex	This guidance provides a revised template for the Preliminary Assessment Review (PAR) form under the MDR. It aims to standardize the assessment process for conformity assessment bodies (CABs) when evaluating applications for designation as notified bodies. The document includes an annex listing the required documents to be submitted with the application.
Preliminary assessment review (PAR) form template (IVDR) ***Annex to Application Form & PAR Template IVDR (List of documents)*** MDCG 2024-7 rev.1 MDCG 2021-15/MDCG 2024-7 Annex	This guidance offers a revised template for the Preliminary Assessment Review (PAR) form under the IVDR. It is designed to harmonize the evaluation process for CABs assessing applications for designation as notified bodies in the field of in vitro diagnostic medical devices. An annex detailing the necessary supporting documents is included.

Title	Overview
Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices regulation (IVDR) ***Annex to Application Form & PAR Template IVDR (List of documents)*** MDCG 2021-16 rev.1 MDCG 2021-16/MDCG 2024-8 Annex	The MDCG has released updated application forms and annexes for conformity assessment bodies (CABs) seeking designation as notified bodies under the MDR and IVDR. These forms require CABs to provide organizational details, technical competence evidence, and quality management system documentation. The annexes list necessary supporting documents, such as personnel qualifications, risk management procedures, and performance evaluation data for IVDs. Authorities use the Preliminary Assessment Review (PAR) template to evaluate applications, ensuring transparency and consistency in the designation process across the EU.
Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR) ***Annex to Application Form & PAR Template MDR (List of documents)*** MDCG 2021-15 rev.1 MDCG 2021-15/MDCG 2024-7 Annex	

Title	Overview
Applied-for scope of designation and notification of a conformity assessment body– Regulation (EU) 2017/745 (MDR) **MDCG 2021-17**	This document defines the specific areas and device categories a conformity assessment body (CAB) seeks to be designated for. This scope outlines the types of medical devices (by risk class and technology) and the corresponding conformity assessment procedures the CAB intends to assess. It ensures that the CAB demonstrates the necessary expertise, resources, and compliance with MDR requirements to handle the applied-for scope. The designation and notification process verifies that the CAB is competent to carry out assessments within the requested scope, ensuring regulatory compliance and safety.
Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 ***MDCG 2023-3 rev.2***	The MDCG 2023-3 rev.2 provides a detailed Q&A on vigilance terms and concepts under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). It clarifies definitions, reporting obligations, and processes related to the vigilance system, including incident reporting, field safety corrective actions (FSCAs), and the role of the Eudamed database. The guidance aims to harmonize vigilance practices, ensuring timely identification and resolution of risks associated with medical devices and in vitro diagnostic devices. It also defines the responsibilities of manufacturers, notified bodies, and other economic operators in maintaining device safety and compliance.

UNITED KINGDOM (UK)

MHRA Releases Guidance on Upcoming Post-Market Surveillance Changes | 15 January 2025

The Medicines and Healthcare products Regulatory Agency (MHRA) has introduced new Post-market surveillance (PMS) regulations for medical devices in Great Britain, effective from June 16, 2025. These regulations focus on enhanced data collection, quicker incident reporting, and clearer obligations for risk management and communication to improve patient safety. They apply to all medical devices, including in vitro diagnostic and active implantable devices, with requirements varying based on risk levels.

The MHRA encourages businesses to begin following the guidance immediately to ensure compliance and welcomes feedback, especially through trade associations, to refine the regulations before they take effect. These changes are part of broader regulatory reforms aimed at better protecting patients and aligning with international standards. The updated regulations will help ensure the ongoing safety and effectiveness of medical devices used in GB.

UK Government Introduces Key Changes in Medical Device Safety and Compliance | 15 January 2025

The UK government is rolling out new regulations for medical devices, focusing on patient safety, access to essential devices, and maintaining the UK's appeal to innovators. The transition to the new framework will be gradual, with CE-marked devices allowed on the market until 2028-2030. New post-market surveillance requirements will be introduced in 2025 to improve safety monitoring, incident reporting, and corrective actions.

Additionally, pre-market regulations are being updated to include stricter requirements for implantable devices, software, and in vitro diagnostics, along with cybersecurity measures and international recognition. These changes aim to create a safer, more innovative market while aligning with global standards.

MHRA Issues Updated Guidance on Periodic Safety Update Reports (PSURs) for Medical Devices | 15 January 2025

In January 2025, the MHRA released updated guidance on Periodic Safety Update Reports (PSURs) for medical devices. The guidance outlines how manufacturers should present and review PSURs, focusing on clear reporting, comprehensive post-market data, and benefit-risk evaluation. Key recommendations include timely submissions, trend analysis for emerging risks, corrective actions, and collaboration with notified bodies. The guidance emphasizes patient safety, urging manufacturers to ensure devices remain safe and effective while adhering to regulatory standards. These updates aim to improve the ongoing monitoring of medical devices in the UK market.

Switzerland Updates In Vitro Diagnostic Medical Device Regulations to Align with EU | 01 January 2024

Starting January 1, 2025, Switzerland's amended Ordinance on In Vitro Diagnostic Medical Devices (IvDO) brings the country into alignment with the EU's extended transitional provisions. The changes extend the validity of EU-issued certificates for certain devices until 2027, 2028, or 2029, depending on risk class, to address delays at notified bodies.

Additionally, there will be a permanent simplification of labeling requirements for devices dispensed by professionals. Healthcare institutions now have until December 31, 2030, to demonstrate that in-house devices or laboratory-developed tests cannot be replaced by CE-marked alternatives.

The device registration requirement, which was initially set to begin earlier, will now take effect on July 1, 2026, six months after the EU's EUDAMED registration obligation. These updates, approved by the Swiss Federal Council in November 2024, ensure continued regulatory equivalence with the EU and support the smooth supply of in vitro diagnostic devices in Switzerland.

Swissmedic Releases Updates on Form Modifications, Notifications, and Reports for MD & IVD | 20 January 2024

Swissmedic has announced updates to the form used for notifications and reporting of Medical Devices (MD) and In Vitro Diagnostic Devices (IVD). These changes aim to simplify the submission process and ensure compliance with Swiss regulations, aligning with European standards.

The updates include clearer guidelines for product documentation and incident reporting. Swissmedic continues to prioritize the safety and quality of medical devices in Switzerland, and industry stakeholders are encouraged to review the new requirements to stay compliant.

SFDA Strengthens Global Position with ICH Management Committee Role | 16 January 2024

The Saudi Food and Drug Authority (SFDA) has made history by becoming the first organization in the Middle East to join the Management Committee of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). This achievement highlights the SFDA's global leadership and expertise, demonstrated by its 42 technical experts contributing to ICH scientific teams. The ICH brings together regulatory authorities and pharmaceutical manufacturers to set guidelines and technical requirements for drug registration and manufacturing, promoting global harmonization. The SFDA now joins international counterparts, including the FDA, WHO, and European Commission, in this prestigious role.

Ethiopia Enhances Drug Registration Process with New Reliance Guidelines | January 2025

The Ethiopia Food and Drug Authority (EFDA) has announced the recognition of 39 National Regulatory Agencies and regional institutions as reference agencies for the abridged registration of medicines under the updated reliance guideline (Version 003), issued on December 2, 2024. The newly approved list includes IGAD MRH and AMRH/AMA, which could serve as a model for other African nations.

Under this guideline, applicants worldwide who have obtained marketing authorization from one or more of the recognized agencies are eligible for an abridged review of their applications. This process is expected to reduce both the standard review timeline and the documentation requirements compared to a full dossier review.

EFDA has set a 90-day target for reviewing abridged applications, provided they are based on approvals from the recognized agencies.

Egypt and Turkey Discuss Joint Efforts to Expand Pharmaceutical Markets | 15 January 2025

The Egyptian Drug Authority held a virtual meeting with the Ambassador of Egypt to Turkey to discuss enhancing bilateral cooperation between the two countries in the pharmaceutical industry. The meeting aimed to strengthen ties and explore new areas of cooperation in vital sectors.

During the discussion, the two sides explored mechanisms for collaboration, including the exchange of expertise in pharmaceutical industries. They also reviewed opportunities to support the entry of Egyptian pharmaceutical products into the Turkish market and discussed leveraging Egypt's strategic location to facilitate Turkish products' access to African and European markets.

The meeting underscored the importance of partnership in advancing the pharmaceutical industry and the potential benefits of cooperation between Egypt and Turkey. Efforts to achieve shared goals were emphasized, and the Egyptian Drug Authority expressed a commitment to continue coordination with the Turkish side. This initiative is part of the Authority's broader efforts to strengthen international cooperation and promote Egyptian pharmaceutical products in global markets.

Egyptian Drug Authority and National Food Safety Authority Clarify Position on Food Supplement Regulation | 12 January 2025

In response to recent discussions about a proposed draft resolution regarding the transfer of responsibility for food supplements, the Egyptian Drug Authority and the National Food Safety Authority clarify that they have not received any request or notification on this matter from any government agencies.

Both authorities reaffirm their ongoing collaboration to ensure the health and safety of Egyptian citizens. They continue to work together using joint mechanisms that enhance the monitoring and regulation of food products and supplements. This partnership is part of their collective efforts to improve oversight and uphold the highest standards of safety and quality.

Additionally, there are joint committees in place to align strategies and make well-organized decisions, ensuring the delivery of safe and effective health services that benefit the Egyptian people. Their shared commitment remains focused on the health and well-being of the citizens of Egypt.

Ultimately, the Egyptian Drug Authority and the National Food Safety Authority stress that their primary objective is to serve the public by providing the best possible health services, while adhering to the highest international standards of regulation and control.

FRANCE

New Simplified Procedure for Exceptional Access to Medical Devices Without CE Marking | 27 January 2025

Starting January 27, 2025, manufacturers wishing to request exceptional access to market medical devices without a CE marking must use a new "simplified procedure" form. This exemption allows certain medical devices, temporarily and exceptionally, to be made available, provided they demonstrate a clear benefit for patient health.

Typically, medical devices must have a CE marking to be sold within the European Union, ensuring compliance with safety and regulatory standards. However, under specific circumstances outlined in Article 59 of Regulation (EU) 2017/745, manufacturers can apply for a waiver to provide healthcare professionals with a device that does not yet have a CE marking. To receive this waiver, manufacturers must prove that the device offers a proven clinical benefit for patients.

The introduction of the simplified procedure form for exemption requests will streamline the process. This form applies to both individual and global exemption requests, helping to standardize data submissions and reduce processing times. A similar procedure for in-vitro diagnostic medical devices will be available soon.
This new approach aims to improve efficiency, ensuring timely access to medical devices that can significantly benefit patient health.

BELGIUM

Updated Guidelines for Labelling and Packaging of Medicinal Products | 14 January 2025

The updated guidelines for the labelling and packaging of medicinal products for human use, announced on January 14, 2025, introduce several important revisions. These updates are in line with the latest European directives and international agreements.

The definition of the medicinal product name has been updated, and there are new requirements for declaring fluorinated greenhouse gases in the list of excipients. Additionally, the guidelines clarify the application of code numbers for narcotic drugs and psychotropic substances, as well as provide more specific instructions for blister packaging, including for empty units and perforated packaging. Lastly, the guidelines now include provisions for the use of QR codes and their corresponding URLs to facilitate mobile scanning technology.

These changes aim to improve the consistency and compliance of medicinal product labelling and packaging.

Obligation for manufacturers to notify interruptions or discontinuations in the supply of medical devices and in vitro diagnostic medical devices | 07 January 2025

Starting January 10, 2025, manufacturers must report interruptions or discontinuations in the supply of medical devices (MDs) and in vitro diagnostic devices (IVDs) if their absence could pose a risk to patient or public health in the EU. This requirement is part of Regulation (EU) 2024/1860.

- Applies to all MDs and IVDs (except custom-made devices) that could cause serious harm if unavailable.
- Manufacturers are responsible for reporting to their competent authority and cannot delegate this legal duty.

- However, they may seek assistance from authorized representatives or other economic operators.
- Belgian manufacturers must submit notifications to FAMHP via the provided form.
- Notifications are mandatory for disruptions after January 10, 2025, but earlier disruptions are encouraged to be reported.

Who Needs to Be Informed?

- Economic operators, healthcare institutions, and professionals directly supplied by the manufacturer.
- The competent authority in the Member State where the manufacturer (or its authorized representative) is registered.

This measure aims to ensure transparency and prevent critical shortages of essential medical devices in the EU market.

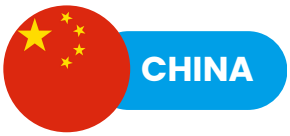
TGA Revises Labelling Standards for Injectable Electrolyte Medicines | 09 January 2025

The Therapeutic Goods Administration (TGA) has updated TGO 91 to improve the clarity of labels for injectable electrolyte medicines (100 mL or less). Labels must now express potassium chloride in millimoles (mmol), with weight also included unless exempt. Other active ingredients must continue to be listed by weight, with their mmol equivalent added.

A transition period runs until November 30, 2026, after which all products must comply. Sponsors must submit a variation request using designated codes. The TGA has also updated guidance documents to support compliance.
Health professionals should expect gradual label changes, with old and new labels appearing simultaneously. Extra care is needed when prescribing and administering these medicines.

Anvisa and DKMA Launch New Phase of Regulatory Collaboration | 22 January 2025

Anvisa and the Danish Medicines Agency (DKMA) are renewing their health sector cooperation for a third phase from April 2025 to March 2028. This phase will focus on technical exchanges covering good clinical practice inspections, medical devices, clinical performance studies, AI in regulation, and antimicrobial resistance management.



China Unveils Guidelines to Reform Drug and Medical Device Regulation | 06 January 2025

China has issued a guideline to reform drug and medical device regulation, aiming to boost the pharmaceutical industry's high-quality development. The plan seeks to create a unified national market and enhance global competitiveness. By 2027, regulatory frameworks and approval processes will be improved, ensuring stricter lifecycle oversight. By 2035, China aims for a modernized regulatory system, stronger innovation, and global leadership in pharmaceuticals.

The guideline includes 24 reform measures in five areas: R&D support, streamlined approvals, stricter supervision, international cooperation, and a regulatory system aligned with industry growth and safety.

ECUADOR

Medicinal products authorized under Section 13(2)(m) of the Pharmaceuticals Act | 24 January 2025

Ecuador has authorized the distribution and use of medicinal products with quality defects that do not pose a threat to health or life. This decision allows such products to remain in circulation for healthcare services under specific regulatory guidelines. The move is aimed at maintaining the availability of medicines while ensuring patient safety. This action follows the country's ongoing efforts to balance public health needs with regulatory oversight.

SÚKL Updates Timeline for eAF Use in Medicinal Product Registration | 24 January 2025

The Registration Section of the State Institute for Drug Control has announced a delay in the recommended use of the web-based eAF for registration changes of medicinal products, now set for February 2025. This tool is already operational for centrally authorized products.

However, users can continue using the web-based eAF. Data will be restored gradually, starting with centrally authorized products on January 20, 2025.

INDIA

Merged existing Medical Devices risk-classification | 01 January 2025

On January 1, 2025, the Central Drugs Standard Control Organization (CDSCO) of India released an updated and consolidated risk-based classification list for medical devices. This comprehensive list merges existing classifications and introduces new entries, aiming to streamline regulatory processes and enhance clarity for stakeholders.

South Korea Enlarges the Scope of Prohibited Labels and Advertisements for Cosmetics | 24 January 2025

As revealed by the Ministry of Food and Drug Safety (MFDS) on January 21, 2025, new prohibited expressions for cosmetic labelling and advertising were published by the revising the Guidelines of Cosmetic Labels and Advertisements.

Modifications	Details
Advisement review standard	The authority will take into consideration of the post titles for the online advertisements when deciding whether the online advertisement is noncompliant.
Newly added prohibited expressions	Expressions related to "designated/recommended/... by medical professionals ***Examples:*** Designed for hospitals , designed for dermatology department, designed for dermatological surgery, for pharmacies.
	Expressions related to human-derived ingredients ***Examples:*** Eosomes, liposomes, etc.
	Untrue or misleading expressions about the product usage methods ***Examples:*** Needles, microneedles , MTS, external genitalia cleansing product labels such as "inner care", etc.
	Expressions about age reduction ***Examples:*** A reduction of 10 years for skin age

CANADA

Canada to Update Cosmetic Notification Form | 21 January 2025

Manufacturers and importers of cosmetics in Canada must adhere to updated regulations requiring them to submit a **Cosmetic Notification Form (CNF)** to Health Canada. This measure is intended to ensure product safety and regulatory compliance.

The CNF must be submitted **within 10 days** of the first sale of a cosmetic in Canada. For imported products, it is strongly recommended that the notification be made before importation to prevent regulatory issues and potential disruptions.

Failure to comply with these regulations can lead to serious consequences. Products that have not been properly notified may be denied entry into Canada, and those already on the market could be removed.

Additionally, non-compliant manufacturers and importers may face increased scrutiny and potential fines under the Cosmetic Regulations of the Food and Drugs Act.

These updated requirements highlight the importance of regulatory compliance in ensuring consumer safety and the lawful distribution of cosmetic products in Canada.

INDONESIA

Indonesia Issues Regulation on Standard Operating Procedures (SOP) for Halal Certification Services for Micro and Small Enterprises (MSEs) | 17 January 2025

On December 31, 2024, Indonesia's Halal Product Assurance Agency (BPJPH) issued and implemented Regulation No. 80 of 2024, introducing revised Standard Operating Procedures (SOP) for halal certification services tailored specifically for Micro and Small Enterprises (MSEs). This new regulation supersedes Regulation No. 61 of 2022 and is aimed at streamlining the halal certification process, making it more accessible, efficient, and cost-effective for MSEs.

The new regulation reduces administrative burdens by standardizing and simplifying the application requirements for MSEs. Clear guidance is provided for MSEs on the documents and steps required to obtain halal certification.

Indonesia Launches Cosmetic Product Notification System 3.0 | 17 January 2025

The Indonesian Cosmetics Notification System 3.0 opened to enterprises on January 2, 2025, and is now in operation. This updated version of the system includes the following key features:

1	**Cosmetic Distribution Permit** • New products • Products for export only • Clustering products
2	**Cosmetic Notification Updates** • Product updates • Updates to cosmetic kits • Updates to products for export only
3	**Standard Certificate/Letter Notification of Company Changes/Variations** • Company variations • Factory variations • Multi-factory variations

4	**Standard Certificate/Letter Notification of Packaging Changes/Variations** • Packaging variations for cosmetic products • Packaging variations for cosmetic kits
5	**Standard Certificate/Letter Notification of Cosmetic Kits** • Cosmetic products kits

The Indonesian Food and Drug Supervisory Agency (BPOM) has issued reminders for companies regarding the updated Notification System 3.0. Companies are advised to pay attention to the following:

1. **New Requirements for Product Submission in Notification System 3.0**

   - The cosmetic application site must be specified based on the intended use of the product.
   - Notifiers are required to provide a link to the Product Information File (PIF) for each product. The link can be secured, with BPOM requesting access when necessary for evaluation.
   - If the new PB UMKU OSS permit ID is not visible, navigate to the Administrator menu, select "OSS permit ID," and click "Inquire Permit ID."
   - If the notification letter does not appear, go to the Administrator menu, enter the product license ID, click "Show," and then select "Query File DS" from the product list.

2. **Key Points for Filling in Ingredients in Notification System 3.0**

   - The ingredient database includes only the INCI name.
   - Ingredients can be searched using either the INCI name or CAS number.
   - The "Percentage" column must be completed for all ingredients.
   - For ingredients listed in Appendices I-IV of the Technical Requirements for Cosmetic Ingredients, the percentage must not be entered as "0.

- When updating a product, ensure the updated formula, including ingredient names and concentrations, matches the previously submitted data.
- If an ingredient is not available in the system, consult the Directorate of Standardization of Traditional Medicines, Health Supplements, and Cosmetics for guidance.

Ethiopian Food and Drug Authority Tightens Rules for Cosmetic Distributors | January 2025

The Ethiopian Food and Drug Authority (EFDA) has updated its requirements for distribution agreements involving manufacturers, third-party suppliers, and local agents. The focus is on addressing issues like multiple suppliers for the same product, false claims of third-country authorization, and duplicate imports.

New requirements include that third-party suppliers must be legally established entities in the manufacturer's country, and these agreements only apply when the manufacturer is not directly involved in registration and distribution. Suppliers must be authorized by the manufacturer, licensed by their home country's regulatory body, and submit a declaration explaining the need for third-party involvement. Only one third-party supplier is allowed per product in Ethiopia. The EFDA will conduct regular inspections, and the tripartite agreements must include all relevant parties.

This updated guidance is still a working document and may undergo further revisions.

ANMAT Warns Against Combining Sunscreens and Insect Repellents | 13 January 2025

A recent report from ANMAT highlights that using sunscreens and insect repellents together is not safe or effective. Their different formulas and application instructions can lead to decreased sunscreen effectiveness and increased irritation and toxicity due to the repellent's active ingredients.

Sunscreen needs frequent reapplication for UV protection, while insect repellents should not be over-applied to avoid toxicity. Some repellent ingredients can also reduce sunscreen effectiveness. Mosquitoes are more active during early mornings and evenings, times when sunscreen is typically not needed.

Therefore, it's advised to apply sunscreen first, wait 20-30 minutes for absorption, and then apply insect repellent, reapplying sunscreen as needed. Both products are regulated by ANMAT as health products.

Anvisa Releases New Guidelines for Cosmetic Surveillance in Brazil | 23 January 2025

Anvisa has published two documents to support the new rules for post-market monitoring of cosmetics in Brazil. The Inspection Manual for Good Cosmetic Surveillance Practices provides detailed guidelines for health inspections within cosmetovigilance, aiming to standardize regulatory practices. The Questions and Answers on RDC 894/2024 addresses industry concerns, offering practical guidance on implementing the regulation. These documents reinforce the safety and quality of cosmetics, promoting collaboration among stakeholders in the production and surveillance system.

List of ISO standards updated in January 2025:

- ISO 11608-4:2022 - Needle-based injection systems for medical use — Requirements and test methods — Part 4: Needle-based injection systems containing electronic
- ISO 23908:2024 - Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods
- ISO 14607:2024 - Non-active surgical implants — Mammary implants — Specific requirements
- ISO 22675:2024 - Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods
- ISO 10009:2024 - Quality management — Guidance for quality tools and their application
- ISO 23675:2024 - Cosmetics — Sun protection test methods — In vitro determination of sun protection factor (SPF)
- ISO 23698:2024 - Cosmetics — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy