

**Predpisy notifikované v Dohode o technických prekážkach obchodu (TBT WTO)
42. týždeň roku 2021**

Číslo/Dátum	Notifikujúca strana	Charakteristika notifikácie	Pripomienková doba
G/TBT/N/BRA/1271 18/10/2021	Brazil	<i>Quality requirements</i> Resolution 1, 13 October 2021 Public Consultation (Consulta Pública 117 de 14/10/2021) to the following draft Resolution of the Energy Efficiency Levels and Indicators Management Committee – CGIEE, stipulating the new Target Program for Air Conditioners.	12/11/2021
G/TBT/N/CHL/577 18/10/2021	Chile	<i>Cocinas domésticas que utilizan leñas</i> NCh 3446:2020 Cocinas domésticas que utilizan leña – Requisitos y métodos de ensayo Esta norma especifica los requisitos relativos al diseño, la fabricación, el montaje, la seguridad, el rendimiento, la potencia, los gases producto de la combustión, las instrucciones y el marcado de las cocinas domésticas que utilizan leña. Esta norma establece los métodos de ensayo tipo para cocinas domésticas que utilizan leña. Esta norma es aplicable a cocinas domésticas de carga manual de hasta 25 kW, cuya función primaria es cocinar y cuya función secundaria es calentar el espacio en el que están instaladas. Esta norma no es aplicable a los artefactos alimentados por tolva o cargados mecánicamente ni a los artefactos que tienen aire de combustión asistido por un ventilador.	17/12/2021
G/TBT/N/EU/845 18/10/2021	European Union	<i>In vitro diagnostic medical devices</i> Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices Regulation (EU) 2017/746 on in vitro diagnostics medical devices (IVD Regulation) will apply from 26 May 2022. It establishes a new regulatory framework for in vitro diagnostic medical devices including conformity assessment procedures. It was notified to the WTO as notification G/TBT/N/EU/72. Due to the additional resources required to address the COVID-19 pandemic, it is now clear that national authorities, health institutions, notified bodies and economic operators will not be in a position to ensure the proper implementation and application of the Regulation from the date of application. With only six notified bodies designated so far, there is a grave shortage of notified body capacity, making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time. In addition, due to COVID-19 travel restrictions, notified bodies were not able to carry out the required on-site audits at the manufacturers' premises to verify the manufacturing and other relevant processes. This risks significant disruption in the supply of a multitude of in	28/10/2021

in vitro diagnostic medical devices (e.g. HIV tests, pregnancy tests or SARS-CoV-2 tests) on the European Union market. The draft measure proposes a staggered set of transition periods for devices that are required to undergo conformity assessment procedures involving a notified body. The length of the transition periods depends on the risk class of the devices, with shorter transition periods for higher risk devices and longer periods for lower risk ones. In addition, the notified draft proposes a deferred application of the requirements for 'in-house devices', i.e. those made and used within the same health institution.

<p>G/TBT/N/PHL/274 18/10/2021</p>	<p>Philippines</p>	<p><i>Products under BPS mandatory certification (electrical products, appliance, building and construction materials, automotive parts, consumer products, among others)</i></p> <p>Draft Administrative Order No.: _____ Series of 2021 Updating of the Reference Standards in Used in the BPS Mandatory Product Certification Schemes</p> <p>This Technical Regulation prescribes the adoption of the latest versions of the reference standards used or entirely new standards to be used in the BPS Mandatory Product Certification Schemes, as follows:</p> <p>1. All standards related to the BPS Mandatory Product Certification Schemes such as but not limited to PNS ISO 9001, PNS ISO/IEC 17020, PNS ISO/IEC 17021-1, PNS ISO/IEC 17025, and PNS ISO/IEC 17065; and</p> <p>2. All relevant and specific standards of the products covered under the BPS Mandatory Product Certification Schemes.</p>	<p>14/12/2021</p>
<p>G/TBT/N/ARE/516 18/10/2021</p>	<p>UAE</p>	<p><i>Air quality measurements</i></p> <p>Technical regulation for controlling of air quality measurements</p> <p>This Regulation applies to laboratories and environmental monitoring networks to measure air pollutants specified in Cabinet Resolution No. (12) of 2006 regarding the system for protecting air from pollution.</p>	<p>17/12/2021</p>
<p>G/TBT/N/ARE/517 18/10/2021</p>	<p>UAE</p>	<p><i>Legal units of measurement</i></p> <p>Technical Regulation for legal units of measurement</p> <p>The provisions of this regulation apply to the legal units of measurement, their symbols and prefixes only, in the following areas: 1- Legal measuring instruments. 2- Prepackaged packages. 3- Commercial exchanges. 4- Legal examinations and measurements. 5- The areas of health, safety and environment 6- Fields of education, and this does not preclude referring to units outside the legal units. 7- Advertisements, publications, books, magazines, and all advertising and media. 8- Documents, contracts, and all official documents issued by public and private official bodies and persons assigned with tasks related to public law.</p>	<p>17/12/2021</p>

G/TBT/N/ARE/518 18/10/2021	UAE	<p><i>Medical and Laboratory Measurement Instruments</i> 17/12/2021</p> <p>Technical Regulations for Mandatory Requirements for Medical and Laboratory Measurement Instruments</p> <p>This technical regulation includes the mandatory requirements for the following legal measuring instruments that are used in laboratories of all kinds, medical clinics, hospitals and health centers. It also applies to instruments imported or manufactured for these purposes, and include: 1- Digital medical thermometers. 2- Medical electric thermometers. 3- Non-overlapping mechanical medical sphygmomanometers. 4- Non-overlapping automated sphygmomanometers. 5- Automatic pipettes. 6- A graduated pipette. 7- A graduated Decanters. 8- Density meters. 9-Bursaries. 10- A graduated cylinders. 11-Medical syringes 12- Measuring Instruments Verified by Reference Materials: - Portable blood glucose meter used for initial diagnostic purposes. 13- Ionizing radiation dosimetry equipment 14- Measuring instruments that have a calibration certificate: -Weights and scales. - Thermometers to measure the temperature of ovens, coolers, water basins, baby incubators, etc. - Sterilizers.</p>
G/TBT/N/ARE/519 18/10/2021	UAE	<p><i>Measuring Instruments for Vehicle speed (radar)</i> 17/12/2021</p> <p>Technical Regulations for Mandatory Requirements of Measuring Instruments for Vehicle speed (radar)</p> <p>The provisions of regulation shall apply to - A very short-wave Doppler radar device to measure the speed of traffic on the roads, - Radar devices operating with laser technology. The regulation also specifies the controls and conditions that must be met by the radar when the results of its measurement are used in administrative, legal or judicial procedures.</p>
G/TBT/N/ARE/520 18/10/2021	UAE	<p><i>National System of Measurement</i> 17/12/2021</p> <p>Cabinet Resolution No. () of 2021 Concerning the National System of Measurement</p> <p>Cabinet Resolution No. () of 2021 Concerning the updating of National System of Measurement.</p>
G/TBT/N/UGA/1464 18/10/2021	Uganda	<p><i>Sanitary appliances, Plastic latrine pan</i> 17/12/2021</p> <p>DUS 2290:2021, Sanitary appliances — Plastic latrine pan — Requirements, First Edition</p> <p>This Draft Uganda standard gives requirements, methods of test and sampling of plastic latrine pans that use mechanical and water seals to close off sub-structure of the pit latrines from the open.</p>
G/TBT/N/BRB/10 19/10/2021	Barbados	<p><i>Electrical lamps</i> 18/12/2021</p> <p>An Act to provide for the phased elimination of the use and sale of inefficient electrical lamps in Barbados Short title: Control of Inefficient Lighting Act, 2021</p> <p>An Act to provide for the phased elimination of the use and sale of inefficient electrical lamps in Barbados. Part I – Preliminary: Provides definitions of the terms</p>

used in the Act Part II – Administration: Provides information on how the Act will be administered with respect to standards and procedures, inspectors, testing, compliance, seizures and warrants. Part III – Electrical Lamps: Provides information on the invoices, labels and packages required for lamps, requirements for the manufacture of lamps, offences and defences. Part IV – Restrictions and Licences: Outlines the prohibition schedule being implemented, exemptions, exempted electrical lamp importation licences, distribution licences, record of licences and production of licences. Part V – Miscellaneous: Provides information on immunity, schedules and regulations. First Schedule: Lists the items defined as an “appliance” in the Act. Licence Fees: Contains the license fees.

<p>G/TBT/N/TPKM/469 19/10/2021</p>	<p>Chinese Taipei</p>	<p><i>Food for human consumption</i> Revised Draft of the Regulations on Nutrition Claim for Prepackaged Food Products The main proposed revisions to the Regulations on Nutrition Claims for Prepackaged Food Products are as follows: 1. Addition of the scope of the definition and terms; 2. Revision to the description of nutrient content claims; 3. Addition of physiological function of nutrients content standard; 4. Revision to the words of claims made by re-hydration products; 5. Requirements for liquid products having two or more nutrition claims to add narrative; and 6. Revision to the words of Table 7.</p>	<p>18/12/2021</p>
<p>G/TBT/N/TPKM/470 19/10/2021</p>	<p>Chinese Taipei</p>	<p><i>Food for human consumption</i> Draft Regulations Governing the Labelling of Restructured and Artificially Marbled Meat Products Based on the provisions of subparagraph 10, paragraph 1, Article 22, and paragraph 2, Article 25 of the Act Governing Food Safety and Sanitation, the MOHW proposes to adopt the labelling requirements for artificially marbled meat products to keep consumers well informed of products they buy.</p>	<p>18/12/2021</p>
<p>G/TBT/N/UKR/204 19/10/2021</p>	<p>Ukraine</p>	<p><i>Hop and hop products</i> The draft Law of Ukraine "On hop and hop products" The draft Law aims to promote effective development of the hop industry, bring national hop production to modern quality level, and simplify business management by improving existing legal norms regulating relations in the sphere of hop growing. The draft Law applies to economic entities whose activities include growing, processing, storage, distribution, export and import of hop products. The adoption of the draft Law will improve implementation of international environmental practices; certification, packaging and labeling of hop products in line with EU requirements; state control in the sphere of hop growing and hop production; simplification of entrepreneurship and deregulation in the sphere of hop growing.</p>	<p>18/12/2021</p>

G/TBT/N/USA/1789 19/10/2021	USA	<p><i>Toxic chemicals</i></p> <p>Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting</p> <p>Proposed rule - In response to a petition filed under the Emergency Planning and Community Right-to-Know Act (EPCRA), EPA is proposing to add 12 chemicals to the list of toxic chemicals subject to the reporting requirements under EPCRA and the Pollution Prevention Act (PPA). EPA believes that each of the 12 chemicals meets the EPCRA criteria. In addition, based on the available bioaccumulation and persistence data, EPA believes that one chemical should be classified as a persistent, bioaccumulative, and toxic (PBT) chemical and designated as a chemical of special concern with a 100-pound reporting threshold.</p>	17/12/2021
G/TBT/N/JAM/103 20/10/2021	Jamaica	<p><i>Prepackaged and prepared foods</i></p> <p>Standard Specification for Processed foods (General)</p> <p>This standard specifies the food safety requirements for a pre-packaged processed food establishment. This standard is not applicable to food: Sold unpackaged, or in an open or uncovered package; Weighed or measured in or counted or placed into the package in the presence of the purchaser; and Fresh fruits, vegetables and ground provisions which have not been peeled, cut or similarly treated.</p>	18/12/2021
G/TBT/N/OMN/452 20/10/2021	Oman	<p><i>Cosmetics; Toiletries</i></p> <p>Draft of ministerial decree</p> <p>The Gulf Standard No. 1943 regarding safety requirements in cosmetics and personal care products is a binding Omani standard.</p>	04/11/2021
G/TBT/N/THA/637 20/10/2021	Thailand	<p><i>Transport exhaust emissions, 43.080 (Commercial vehicles)</i></p> <p>Draft Ministerial Regulation on Light Motor Vehicles Installed with LPG/NG Retrofit Systems: Safety Requirements; Emission from Engine (TIS 3055 - 2563(2020))</p> <p>The draft ministerial regulation mandates light motor vehicles installed with LPG/NG retrofit systems to conform with the standard for Light Motor Vehicles Installed with LPG/NG Retrofit Systems: Safety Requirements; Emission from Engine (TIS 3055 - 2563(2020)). This draft standard covers only light motor vehicles installed with LPG/NG retrofit systems on vehicles equipped with positive ignition engines or with compression ignition engines. This draft standard excludes dual-fuel vehicles. It specifies general and technical requirements, type approval of vehicles, and marking and labelling.</p>	
G/TBT/N/THA/638 20/10/2021	Thailand	<p><i>Motorcycles and mopeds</i></p> <p>Draft Ministerial Regulation on Motorcycle Exhaust Muffler's Part (TIS 3226 - 25XX(20XX))</p> <p>The draft ministerial regulation mandates motorcycle exhaust muffler's part to conform with the standard for Motorcycle Exhaust Muffler's Part (TIS 3226 -</p>	

		25XX(20XX)). This draft standard covers only motorcycle exhaust muffler's part, including exhaust pipe, exhaust manifold and exhaust silencer, of motorcycle category L3 L4 and L5. It specifies general requirements, materials, marking and labelling, sampling and criteria for conformity, and testing.	
G/TBT/N/THA/639 20/10/2021	Thailand	<p><i>Industrial products</i></p> <p>Ministerial Regulation on Fee Exemption for Conformity Assessment Bodies, B.E. 2564 (2021) Issued under the National Standardization Act B.E. 2551 (2008)</p> <p>Due to the situation of Coronavirus disease (COVID-19) pandemic, Thai Industrial Standards Institute (TISI), Ministry of Industry issued the regulation to exempt fees for conformity assessment bodies, prescribed in the Ministerial Regulation on Accreditation Fees for Conformity Assessment Bodies B.E. 2552 (2009) until 30 April 2022.</p>	
G/TBT/N/THA/640 20/10/2021	Thailand	<p><i>Industrial products</i></p> <p>Ministerial Regulation on Fee Exemption for a License and a Substitution of License, B.E. 2564 (2021) Issued under the Industrial Product Standards Act (No. 7), B.E. 2558 (2015)</p> <p>Due to the situation of Coronavirus disease (COVID-19) pandemic, Thai Industrial Standards Institute (TISI), Ministry of Industry issued the regulation to exempt fees for a license and a substitution of license, prescribed in the Ministerial Regulation on Fees for a License and a Substitution of License, B.E. 2548 (2005) until 30 April 2022.</p>	
G/TBT/N/USA/1790 20/10/2021	USA	<p><i>Marine engineering</i></p> <p>Updates to Marine Engineering Standards</p> <p>Notice of proposed rulemaking - The Coast Guard proposes to incorporate by reference updated marine engineering standards and eliminate outdated or unnecessarily prescriptive regulations in Title 46 of the Code of Federal Regulations (CFR) subchapter F. This proposed rule is part of a continuing effort for regulatory reform that increases compliance options for the regulated public while providing a cost savings to the regulated public and the U.S. government.</p>	20/12/2021
G/TBT/N/BDI/158 21/10/2021	Burundi	<p>ICS codes: 71.060.30 (Acids)</p> <p>DEAS 122: 2021, Sulfuric acid — Specification, Second Edition</p> <p>This Draft East African Standard specifies requirements, sampling and test methods for sulfuric acid. This standard covers four grades of sulfuric acid namely, technical, battery, pure and analytical reagents.</p>	20/12/2021
G/TBT/N/BDI/159 21/10/2021	Burundi	<p>ICS codes: 71.040.30 (Chemical reagents)</p> <p>DEAS 123: 2021, Distilled water — Specification, Second Edition</p> <p>This Draft East African Standard prescribes the requirements, sampling and test methods for distilled water.</p>	20/12/2021

G/TBT/N/BDI/160 21/10/2021	Burundi	ICS codes: 87.080 (<i>Inks. Printing inks</i>) DEAS 345: 2021, Toluene — Specification, Second Edition This Draft East African Standard prescribes the requirements, sampling and test methods for toluene.	20/12/2021
G/TBT/N/BDI/161 21/10/2021	Burundi	ICS codes: 65.100.01 (<i>Pesticides and other agrochemicals in general</i>) DEAS 361: 202, Carbaryl dusting powders — Specification, Second Edition This Draft East African Standard prescribes the requirements, sampling and test methods for carbaryl dusting powders.	20/12/2021
G/TBT/N/BDI/162 21/10/2021	Burundi	ICS codes: 71.100 (<i>Products of the chemical industry</i>) DEAS 384: 2021, Disinfectants and antiseptics - Glossary, Second Edition This Working Draft East African Standard defines the terms used in the disinfectant and antiseptic industry.	20/12/2021
G/TBT/N/RWA/549 21/10/2021	Rwanda	ICS codes: 71.060.30 (<i>Acids</i>) DEAS 122: 2021, Sulfuric acid — Specification, Second Edition This Draft East African Standard specifies requirements, sampling and test methods for sulfuric acid. This standard covers four grades of sulfuric acid namely, technical, battery, pure and analytical reagents.	20/12/2021
G/TBT/N/RWA/550 21/10/2021	Rwanda	ICS codes: 71.040.30 (<i>Chemical reagents</i>) DEAS 123: 2021, Distilled water — Specification, Second Edition This Draft East African Standard prescribes the requirements, sampling and test methods for distilled water.	20/12/2021
G/TBT/N/RWA/551 21/10/2021	Rwanda	ICS codes: 87.080 (<i>Inks. Printing inks</i>) DEAS 345: 2021, Toluene — Specification, Second Edition This Draft East African Standard prescribes the requirements, sampling and test methods for toluene.	20/12/2021
G/TBT/N/RWA/552 21/10/2021	Rwanda	ICS codes: 65.100.01 (<i>Pesticides and other agrochemicals in general</i>) DEAS 361: 202, Carbaryl dusting powders — Specification, Second Edition This Draft East African Standard prescribes the requirements, sampling and test methods for carbaryl dusting powders.	20/12/2021
G/TBT/N/RWA/553 21/10/2021	Rwanda	ICS codes: 71.100 (<i>Products of the chemical industry</i>) DEAS 384: 2021, Disinfectants and antiseptics - Glossary, Second Edition This Working Draft East African Standard defines the terms used in the disinfectant and antiseptic industry.	20/12/2021
G/TBT/N/TZA/646 21/10/2021	Tanzania	ICS codes: 71.060.30 (<i>Acids</i>) DEAS 122: 2021, Sulfuric acid — Specification, Second Edition	20/12/2021

			This Draft East African Standard specifies requirements, sampling and test methods for sulfuric acid. This standard covers four grades of sulfuric acid namely, technical, battery, pure and analytical reagents.	
G/TBT/N/TZA/647 21/10/2021	Tanzania	ICS codes: 71.040.30 (<i>Chemical reagents</i>) DEAS 123: 2021, Distilled water — Specification, Second Edition	This Draft East African Standard prescribes the requirements, sampling and test methods for distilled water.	20/12/2021
G/TBT/N/TZA/648 21/10/2021	Tanzania	ICS codes: 87.080 (<i>Inks. Printing inks</i>) DEAS 345: 2021, Toluene — Specification, Second Edition	This Draft East African Standard prescribes the requirements, sampling and test methods for toluene.	20/12/2021
G/TBT/N/TZA/649 21/10/2021	Tanzania	ICS codes: 65.100.01 (<i>Pesticides and other agrochemicals in general</i>) DEAS 361: 202, Carbaryl dusting powders — Specification, Second Edition	This Draft East African Standard prescribes the requirements, sampling and test methods for carbaryl dusting powders.	20/12/2021
G/TBT/N/TZA/650 21/10/2021	Tanzania	ICS codes: 71.100 (<i>Products of the chemical industry</i>) DEAS 384: 2021, Disinfectants and antiseptics - Glossary, Second Edition	This Working Draft East African Standard defines the terms used in the disinfectant and antiseptic industry.	20/12/2021
G/TBT/N/UGA/1465 21/10/2021	Uganda	ICS codes: 71.060.30 (<i>Acids</i>) DEAS 122: 2021, Sulfuric acid — Specification, Second Edition	This Draft East African Standard specifies requirements, sampling and test methods for sulfuric acid. This standard covers four grades of sulfuric acid namely, technical, battery, pure and analytical reagents.	20/12/2021
G/TBT/N/UGA/1466 21/10/2021	Uganda	ICS codes: 71.040.30 (<i>Chemical reagents</i>) DEAS 123: 2021, Distilled water — Specification, Second Edition	This Draft East African Standard prescribes the requirements, sampling and test methods for distilled water.	20/12/2021
G/TBT/N/UGA/1467 21/10/2021	Uganda	ICS codes: 87.080 (<i>Inks. Printing inks</i>) DEAS 345: 2021, Toluene — Specification, Second Edition	This Draft East African Standard prescribes the requirements, sampling and test methods for toluene.	20/12/2021

G/TBT/N/UGA/1468 21/10/2021	Uganda	<p><i>ICS codes: 65.100.01 (Pesticides and other agrochemicals in general)</i></p> <p>DEAS 361: 202, Carbaryl dusting powders — Specification, Second Edition</p> <p>This Draft East African Standard prescribes the requirements, sampling and test methods for carbaryl dusting powders.</p>	20/12/2021
G/TBT/N/UGA/1469 21/10/2021	Uganda	<p><i>ICS codes: 71.100 (Products of the chemical industry)</i></p> <p>DEAS 384: 2021, Disinfectants and antiseptics - Glossary, Second Edition</p> <p>This Working Draft East African Standard defines the terms used in the disinfectant and antiseptic industry.</p>	20/12/2021
G/TBT/N/USA/1791 21/10/2021	USA	<p><i>Hearing aids</i></p> <p>Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids</p> <p>Proposed rule - The Food and Drug Administration (FDA, we, or the Agency) is proposing to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids. Specifically, we propose to define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with a new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements. This action, if finalized, would more clearly define prescription hearing aids; however, it would not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.</p>	18/01/2022
G/TBT/N/BRA/1272 22/10/2021	Brazil	<p><i>Agricultural Products – ICS Code(s): 13, 65</i></p> <p>Resolution number - RDC - 571, 15 October 2021</p> <p>This resolution disposes about the monographs of the active ingredients for pesticides, household cleaning products and wood preservatives, and their regulatory process. This regulation will be also notified to the SPS Committee.</p>	
G/TBT/N/BRA/1273 22/10/2021	Brazil	<p><i>Agricultural Products - ICS Code(s): 13, 65</i></p> <p>Normative Instruction 103, 19 October 2021</p> <p>This normative instruction disposes about the Monograph List of Active Ingredients for Pesticides, Household Cleaning Products and Wood Preservers. This regulation will be also notified to the SPS Committee.</p>	

G/TBT/N/KOR/1000 22/10/2021	Korea	<p data-bbox="643 190 754 215"><i>Cosmetics</i></p> <p data-bbox="643 221 1062 248">Amendments to the “Cosmetics Act”</p> <p data-bbox="643 253 1225 768">Under the current law, Braille labeling may be placed on the container or packaging of cosmetic products to be accessible for blind or visually impaired consumers. However, the current law does not require detailed information in Braille other than the name of the product or the trade name of the business operator, which makes it difficult for persons with vision impairment to access accurate product information when purchasing cosmetics. Also, persons with hearing loss experience similar accessibility issues when purchasing cosmetic products. Therefore, in order to provide detailed information of cosmetic products to persons with vision or hearing impairments, business operators are required to display detailed product information in Braille and text-to-speech conversion codes on the container or packaging of cosmetic products.</p>	21/12/2021
G/TBT/N/KOR/1001 21/10/2021	Korea	<p data-bbox="643 801 823 826"><i>Medical Devices</i></p> <p data-bbox="643 833 1225 891">Amendments to the “Enforcement Rule of the Medical Devices Act”</p> <p data-bbox="643 896 1225 1532">The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is amending the “Enforcement Regulations of Medical Devices Act” as stated below: The Medical Devices Act was revised and promulgated on July 20, 2021, to mandate the sealing of medical devices that may be contaminated from an opened or compromised package and to ban the sale of medical devices that are packaged in opened or unsealed containers. Accordingly, the Enforcement Regulations of the Medical Devices Act are to be revised to define the medical devices that shall be subject to package sealing as well as the sealing requirements. The Medical Devices Act was revised and promulgated on August 17, 2021, to replace the Re-examination system (for newly developed medical devices, etc) with the Post-Market Surveillance system (for newly developed medical devices, etc). Accordingly, the Enforcement Regulations of the Medical Devices Act are to be revised to provide operational guidance and to define the medical devices that are exempt from post-market surveillance.</p>	21/12/2021