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Regional Medical Device Security through Safety Standard Harmonization

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Abstract

The 2019 global pandemic has served as a wake-up call for policymakers regarding the importance of prioritizing medical device security. As the virus spread, it was depleting supplies of key vital medical devices around the world. Many nations have then decided to impose export restrictions on certain pandemic-prevention-related medical devices. This paper argues that harmonization of regional safety standards could be another means for countries to promote regional medical device security. We examine how the EU Medical Device Regulation and ASEAN Medical Device Directive, regional efforts to harmonize safety standards, facilitate regional trade and contribute to the improvement of regional medical device security, using the gravity modeling framework. The key finding is that EU version of safety standard harmonization promotes both regional and global trades, while ASEAN version can encourage only the regional, not the global one.

JEL Classification: F10, F14, I18
Keywords: Medical Device Trade, Safety Standard Harmonization, EU, ASEAN, COVID-19

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1. Introduction

The COVID-19 pandemic has prompted policymakers to recognize the critical importance of placing medical device[2] security at the top of their priority list. As the virus spread, global supplies of critical medical devices were depleted. Demand for medical devices such as face masks, personal protection equipment, and respirators was increasing in the early pandemic era. To cope with the emergency of medical device shortages, nearly 390 temporary trade restrictions and measures were imposed in 2020 (UNCTAD, 2021). Evenett (2020) finds that national protectionism hinders medical device trade, while Espitia *et al*. (2020) discovers that export restrictions disrupt global supply chains and raise prices of medical devices. Many purpose that free trade and trade policy are a part of the solution (Baldwin and Tomiura, 2020; Bown, 2020; Evenett, 2020). This paper argues that harmonization of safety standards among countries could be another approach for countries to promote regional medical device security.

The issue of medical device security pertains to the adequacy of a country's supply of medical equipment to meet the demands of public health services under normal circumstances as well as during times of crisis. The promotion of medical device security can be facilitated by the government through the encouragement of domestic production or the facilitation of imports from global sources. Increasing the importation of medical devices from countries within the same region is an additional potential solution. According to UNCTAD (2021), countries have several options at their disposal to enhance regional trade in medical equipment. These include the establishment of a regional trade agreement, collaboration on regulatory frameworks, and the harmonization of safety standards. Our research focuses on examining the impact of harmonizing safety standards on the flow of trade.

Harmonizing safety standards can improve medical device security by facilitating intra-regional trade and imports from non-regional trade partners. In principle, standardization plays a crucial role in promoting medical device trade by lowering trade costs such as information costs, specification costs, and conformity assessment costs. Recently, the EU and several ASEAN members adopted Regulation (EU) 2017/745 and the ASEAN Medical Device Directive (AMDD) to harmonize their medical device safety standards. Nonetheless, there is no prior literature examining the safety standard harmonization on medical device imports, especially during a health pandemic.

The gravity model is utilized in this study to examine the effects of Regulation (EU) 2017/745 and ASEAN Medical Device Directive (AMDD) on trade patterns in the medical device industry. The objective is to determine whether these efforts enhance commerce within the region and/or with other global markets. Medical devices can be classified into four distinct classes, namely single-use medical devices, reagent and test kits, implantable single-use medical devices, and durable

[2] See Table A1 in the Appendix for the list of medical device products.

medical devices. The initial two can be categorized as low-risk, whereas the latter two can be labeled as high-risk for patients and users. In order to get insight into the distinct impacts of harmonization on various categories of medical devices, we endeavor to comprehend the diverse ramifications associated with different risk level classifications.

We find that Regulation (EU) 2017/745 has the potential to facilitates trade movements of medical devices across all classifications, both within the European Union and globally. Conversely, the AMDD exclusively supports trade flows only within the region, without extending its influence to ASEAN medical device imports from non-regional countries. One potential rationale for the disparity observed in the harmonization of the two frameworks is that Regulation (EU) 2017/745 applies uniformly across all member states, while the AMDD serves as a guiding document without a mutual recognition agreement. In the context of medical devices, it is important to note that if a product receives approval inside a member state of the European Union (EU27), it is eligible for marketing across all member states. Conversely, if a medical device obtains approval within a member state of the ASEAN, it is limited to marketing just within that specific country and not in any other member states. It is imperative for firms to adhere to a standardized procedure when entering a foreign market for product marketing purposes. Therefore, the advantages of harmonization within the European Union (EU27) are greater in comparison to those within the ASEAN.

In contrast to the research conducted by Vo and Le (2021) on the welfare implications of protectionist policies for COVID-19 test kits, our study focuses on examining the impact of regulatory cooperation on trade flows. To the best of our knowledge, there is a lack of comprehensive research examining the impact of safety standard harmonization on the trade of medical devices both within the region and globally. This study is the first attempt to empirically investigate the effects of the subject matter.

This paper is organized as follows. Section 2 gives a general history of safety standard harmonization efforts until the present endeavors. Section 3 describes trends and patterns of medical devices. Next, we purpose the analytical framework on regional medical device security and trade. Model specification is detailed in section 5. For data sources, variable construction, and econometric issues, we discuss them in section 6. Results are rationalized in section 7. In the last section, we conclude.

2. Safety Standard Harmonization

Numerous international endeavors have been made to establish a universal safety benchmark within the medical device sector. The International Organization for Standardization (ISO) was founded in 1947 with the primary objective of establishing standards for items that require health and safety considerations, particularly in the realm of medical devices. Nonetheless, the industry

became divided into many product categories, resulting in a situation where individual countries established their own set of standards. The Global Harmonization Task Force (GHTF) was established in 1992 as a consortium comprising regulatory authorities from many nations and representatives from the medical device industry. Its primary objective was to foster regulatory harmonization and enhance the uniformity of regulations across the sector. The GHTF was officially dissolved in the year 2012 and subsequently succeeded by the International Medical Device Regulators Forum (IMDRF), which was established with the participation of a larger number of countries across the globe. Recommendations have been made to match guidelines for quality management systems for medical device manufacturers with the ISO 13485 standard. The IMDRF has consistently advocated for the harmonization of safety standards.

In addition to the establishment of a worldwide consortium for medical device regulations, governments within a particular region attempt to undertake similar initiatives to facilitate regional trade. The EU Medical Device Regulation 2017/745 and the ASEAN Medical Device Directives (AMDD) are two regional initiatives[3] aimed at achieving harmonization of safety standards for medical device manufacturers. Both prioritize patient safety through the implementation of a comprehensive pre-market assessment and post-market surveillance of medical devices. Manufacturers are required to furnish extensive documentation, encompassing clinical proof, to ensure the safety and effectiveness of their equipment. The adoption of risk-based classification is utilized to group medical equipment into distinct classes (Niemiec, 2022; Schoener and Hoxey, 2019). The greater the risk to patients and users, the more stringent the registration and approval requirements (Table 1).

Table 1 Risk-based classification in Regulation (EU) 2017/745 and AMDD

Risk Level	Regulation (EU) 2017/745	AMDD
High	III	D
Moderate/High	IIb	C
Low/Moderate	IIa	B
Low	I	A

Source: Author's compilation

The mutual recognition agreement ensures compliance with Regulation (EU) 2017/745. The sale of a medical device across all EU member states is permissible if it has obtained approval from any notified body within the EU. The establishment of a harmonized regulatory framework is expected to enhance the facilitation of trade in medical equipment (Shatrov and Blankart, 2022). Regulation (EU) 2017/745 also encompasses a comprehensive premarket obligation, heightened

[3] The European Union (EU) Medical Device Regulation, officially known as Regulation (EU) 2017/745, is applicable to all 27 member states of the European Union. The ASEAN Medical Device Directive pertains to the member states of the Association of Southeast Asian Nations (ASEAN), encompassing Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam.

inspection, and diligent post-market surveillance. Ben-Menahem *et al*. (2023) argued that the implementation of the European Union Medical Device Regulation (EU MDR) should serve as a catalyst for manufacturers to increase their investments in research and development (R&D), hence fostering a favorable environment for product selection. Nevertheless, it is important to note that this phenomenon may also enhance the obstacles faced by enterprises lacking substantial financial resources, thereby deterring competitive forces within the medical device sector.

The ASEAN Medical Device Directive was formulated and signed in the year 2015. In its essence, directive inherently lacks rigid implementations for its constituents. The specific date of adoption may differ across countries due to variations in the time taken by each member to develop and enact a new bill in accordance with the directive. Table 2 displays the respective years in which each member country within the ASEAN issued an instrument of ratification. Singapore has been in compliance with the guideline since 2015, but Indonesia and Myanmar adopted it in 2018, followed by Malaysia in 2020. Thailand and the Philippines subsequently implemented the directive in 2021. The countries of Vietnam, Cambodia, and Laos have just issued documents of acceptance and are currently in the process of ensuring compliance with the directive. One distinguishing feature of the AMDD, in comparison to Regulation (EU) 2017/745, is its deviation from the mutual recognition agreement for all member states. This deviation necessitates manufacturers to submit conformity assessment documents separately in each respective country. The validation of a medical device in one nation does not inherently imply its immediate approval in another.

Table 2 Effective Date of Regulation (EU) 2017/745 and AMDD

Countries	**Signed**	**Effective**	**Acceptance**	**Ratification**
EU27	2017	2021		
ASEAN	2015			
Laos			2015	
Vietnam			2016	
Cambodia			2019	
Brunei			n/a	
Singapore				2015
Indonesia				2018
Myanmar				2018
Malaysia				2020
Thailand				2021
the Philippines				2021

Source: European Union and ASEAN

Efforts have been undertaken at the regional level to establish a cohesive set of safety standards for medical devices. Both the European Union (EU) and the ASEAN venture to enhance the

facilitation of medical device trade through the utilization of risk-based classification, pre-market requirements, and post-market surveillance. In the next section, we present an overview of the regional medical device trades between the ASEAN and EU27 regions, spanning from 1990 to 2022. Examining the trends and patterns of imports of medical devices will enhance our understanding of the impact of harmonizing safety standards on the trade dynamics of medical devices.

3. Trends and Patterns of Medical Device Imports

Trade flows of medical device have been on the rise in the past decades. There are various socio-economic factors that contribute to this expansion. The increasing global population and the growing proportion of elderly individuals contribute to an elevated need for medical device among patients and users (WHO, 2022). The prevalence of non-communicable diseases, such as cardiovascular disease and arthritis, among office employees has been observed to increase because of changes in working behavior (WHO, 2022). New advancements in manufacturing technology also encourages firms to expand their medical device production capacity (Donzé, 2022).

Figure 1 shows the import value of medical devices for 105 countries from 1990 to 2022. The medical equipment trade saw declines as a result of both the economic crisis in 2008 and the public health crisis in 2020. The COVID-19 pandemic has had a significant impact on the trade flow of medical equipment. This is mostly due to the increased occupancy of hospitals with COVID-19 patients, leading to the suspension of treatments for individuals with non-COVID-19 related ailments (U.S. International Trade Commission, 2020). Consequently, there has been a decrease in overall demand for medical devices, particularly durable ones which accounted for about 80 percent of the total import demand in 2019. It has been observed that during the COVID-19 pandemic, there was an increase in the demand for single-use medical devices, as well as reagent and test kits. This surge in demand can be attributed to the widespread shortages of these essential supplies in numerous nations globally.

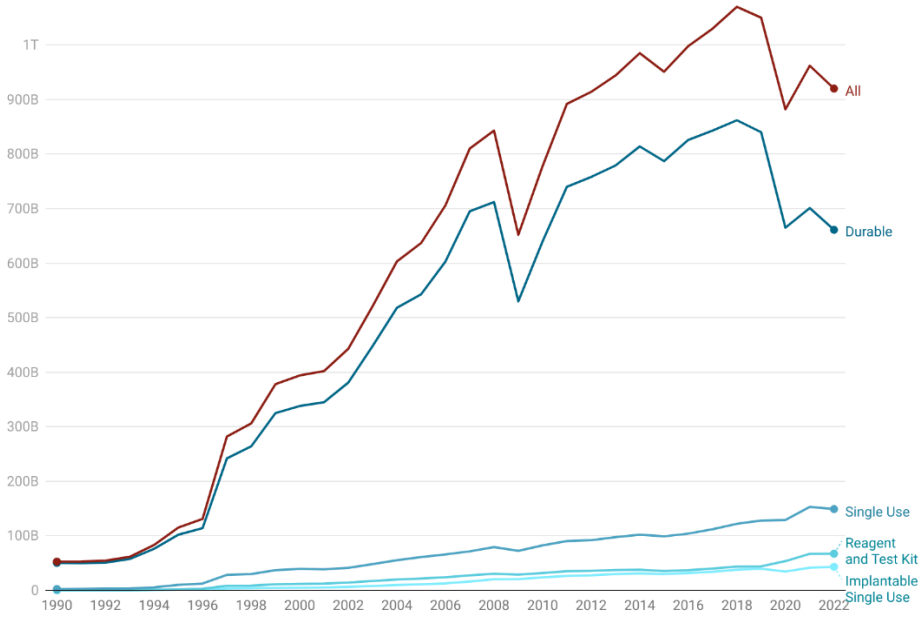

Fig. 1. Import Value of Medical Devices (USD), 1990-2022

Source: S&P Global Market Intelligence

Table 3 presents the distribution of medical device imports among the trading partners of the European Union. The EU27 has demonstrated a significant degree of intra-regional dependence, as evidenced by the fact that over 70 percent of EU27 medical device imports have been traded among member states within the same region from 1996 to 2022. The current trend in EU27 medical device imports reveals a notable increase in China's market share, which has grown from approximately 1 percent in 1996 to 6.56 percent in 2022. The proportion of imports from the ASEAN to the EU27 has consistently constituted a relatively little fraction. Conversely, the import share from the US to the EU27 has been steady over the course of previous decades.

Table 3 Trading partner share of EU27 medical device imports, 1996-2022[(a)]

Trading Partners of EU27	**Medical device import share of EU27 (%)**					
	1996-2000	**2001-2005**	**2005-2010**	**2011-2015**	**2016-2020**	**2021-2022**
EU27	70.44	73.72	73.72	70.35	70.45	70.09
ASEAN	0.41	0.48	0.48	0.87	1.13	1.82
US	6.73	6.74	6.74	7.77	7.35	7.87
China	1.05	1.34	1.34	3.31	3.96	6.56
All	100.00	100.00	100.00	100.00	100.00	100.00

Note: (a) Five-year average of medical device import share

Source: S&P Global Market Intelligence

In contrast to the EU27, the ASEAN medical device import has not been heavily dependent on intra-regional trade. This is evident from the data presented in table 4, where it is observed that approximately 20 percent of the regional trade is attributed to ASEAN. The EU and China are considered significant commercial partners for the ASEAN. Over the past two decades, China's competitiveness has witnessed a notable rise, observed by its growing percentage of imports to the ASEAN. Specifically, China's share of ASEAN medical device imports has increased substantially, rising from 2.3 percent in 1996 to 23.1 percent in 2022. The proportion of imports from the United States to the ASEAN has experienced a decline since the 2010s, potentially attributable to increased competition from China.

Table 4 Trading partner share of ASEAN medical device imports, 1996-2022[(a)]

Trading Partners of ASEAN	Medical device import share of ASEAN (%)					
	1996-2000	2001-2005	2005-2010	2011-2015	2016-2020	2021-2022
EU27	19.60	17.90	17.98	20.67	17.53	14.24
ASEAN	10.73	18.17	23.52	24.18	25.40	25.92
US	13.33	11.77	11.59	12.57	12.49	11.55
China	2.30	5.34	7.70	9.74	15.00	23.13
All	100.00	100.00	100.00	100.00	100.00	100.00

Note: (a) Five-year average of medical device import share
Source: S&P Global Market Intelligence

The European Union and the ASEAN exhibit contrasting import structures, although they both demonstrate a commitment to harmonizing safety standards for medical device within their respective regions. This study aims to analyze the impacts of safety standard harmonization in both regions. In the subsequent section, we will provide an empirical elucidation of the analytical framework pertaining to trades involving medical devices.

4. Analytical Framework

We start our analysis by defining the regional medical device security. Medical device security refers to the state in which a nation possesses an enough supply of medical devices to effectively deliver public health services during both normal operating conditions and periods of crisis, such as pandemics. The alleviation of the medical device shortage can be achieved through supporting domestic production, importing more from nations within the same region, or from the rest of the world. Hence, we posit that the achievement of regional medical device security can be facilitated by fostering regional trade in medical devices, with safety standard harmonization serving as a means to encourage such trade. In order to have a comprehensive understanding of regional trade, it is imperative to establish a foundation in the context of international trade.

The demand and supply frameworks are employed for the analysis of international trade in medical devices. On the demand side, an increase in population size and the old corresponds to a greater requirement for medical equipment consumption, since the expanding number of prospective patients and users necessitates it (WHO, 2022 and Donzé, 2022). The demand for medical devices is influenced by a higher level of income, as individuals with greater financial resources want access to improved and more advanced medical gadgets for their treatment (WHO, 2022). The medical device sector, from a supply perspective, is primarily focused on research and development and must adhere to established safety standards (Donzé, 2022). The implementation of safety standards, intended to safeguard the well-being of patients and users, inadvertently gives rise to an associated trade cost (OECD, 2017). Regulatory heterogeneity has been a persistent phenomenon for many years, as numerous countries establish their own distinct sets of laws and regulations.

Regulatory divergence in medical device industry gives rise to at least three trade costs (OECD, 2017). First, information cost befalls because firms need to identify, gather, and process all the necessary information pertaining to the regulatory mandates of the destination country. Second, specification cost accrues to firms supplying medical devices to many countries with various regulations such as production process, quality management system, and labelling requirement. The adherence to various regulations imposes additional expenses on firms and impedes their inclination to engage in international trade.

Third, conformity assessment cost is incurred to firms submitting evidence to authorities to verify that the products follow the safety standard set in the destination countries. Conformity assessment cost encompasses two distinct dimensions. The initial part relates to the subject matter, encompassing laboratory testing methodologies and clinical sample techniques. Various nations may impose distinct criteria. While the home country may report identical results, the destination country may necessitate other methodologies and further clinical testing from the manufacturer. The second part is to the identity of the individuals involved, specifically referring to test results issued by reputable testing institutes accompanied by valid certification. The destination country may impose a requirement on enterprises to provide test results that have been certified exclusively by testing centers that are officially recognized by the government. These two factors contribute to additional trade expenses that foreign enterprises must bear.

The market registration requirements and safety standards established by the EU Medical Device Regulation are mandatory for all companies. Upon approval, the application provides access to all EU member states. Therefore, the trade costs associated with information, specification, and conformity assessment could be minimized. It is, however, not the case for the ASEAN. The application of safety standards and market registration requirements remains consistent across all member states that submit the instrument of ratification. However, firms are required to bear the

costs associated with meeting safety standards anew if they intend to market their products in multiple countries, as the registration of medical devices is limited in validity to the country of registration for each respective firm. As a result, in the ASEAN region, the cost of conformity assessment could be partially reduced while the cost of information and specifications could be fully minimized. In the next section, we will show the empirical framework employed to analyze the impact of regional safety standard harmonization on the trading of medical devices.

5. Model Specification

In this study, we employ the gravity model to examine the impact of regional safety standard harmonization on the trade of medical devices. Following Yotov *et al.*(2016), bilateral trade flows are influenced by two primary factors. The first is *size factors of country-pair*: the larger the exporters from the country *i* are, the more exports they can supply to country *j*, and countries with higher income can import more products from all exporters. Therefore, the bilateral trade flows depend positively on the size factors. The second is *trade cost factors* including bilateral trade costs between country-pair and multilateral resistance (MR)[4].

The four-dimensional panel analysis allows us to formulate the econometric model in the following equation.

$$MD_{i,j,p,t} = \exp\Big\{\alpha_0 + \alpha_1 D_{HA\,j,t} + \alpha_2\left(D_{HA\,j,t} * D_{ASEAN\,i,j}\right) + \alpha_3\left(D_{HA_{j,t}} * D_{EU_{i,j}}\right) + \alpha_4 \log Y_{i,t} + \alpha_5 \log E_{j,t} + \alpha_6 Dist_{i,j} + \alpha_7 Language_{i,j} + \alpha_8 Colony_{i,j} + \alpha_9 Contiguity_{i,j} + \alpha_{10} PTA_{i,j,t} + \sum_t \beta_t BOD_{i,j,t} + \sum_k \gamma_k MR^k_{i,j,t} + \theta_p + \theta_t\Big\} u_{i,j,p,t}$$

where $MD_{i,j,p,t}$, denotes the bilateral trade flow of medical device product p from exporting country i to importing country j at time t. $D_{HA\,j,t}$ is the dummy variable of the safety standard harmonization, assuming the value of 1 if the importing country j implements safety standard harmonization. $D_{ASEAN\,i,j}$ and $D_{EU\,i,j}$ denote the dummy variables, taking the value of 1 if a country pair i and j is in ASEAN or EU, respectively. $Y_{i,t}$ is income of exporting country i. $E_{j,t}$ is income of importing country j. $Dist_{i,j}$ is the geographical distance between countries i and j. $Language_{i,j}$ is a common language, taking the value 1 if a country pair shares the same formal language. $Colony_{i,j}$ is a colony tie, being the value 1 if a country pair has colonial relationship in the past. $Contiguity_{i,j}$ is contiguity, being the value 1 if a country pair shares the same border. $PTA_{i,j,t}$ is the trade policy variable being the value 1 if a country pair joins the same preferential

[4] The MR term expresses the role of the relative bilateral trade costs to average costs that country pairs are faced with their other trading partners.

trade agreement. $BOD_{i,j,t}$ is globalization effect, being the product of a time dummy and time-invariant binary variable taking the value 1 if the source and destination countries are different countries and the value 0 if i and j are the same country. $MR_{i,j,t}^{k}$ is the multilateral resistance associated with each of the bilateral trade costs. θ_p and θ_t are product-specific and time-specific fixed effects. u is the error term.

According to Yotov *et al*. (2016), the dependent variable (MD) includes both international and intranational trade flow data to ensure theoretical consistency. Also, the main variable of interest is the safety standard harmonization ($D_{HA_{j,t}}$), measuring the time period that an importing country implements or ratifies a safety standard harmonization, such as EU27 in 2021, Singapore in 2015, Thailand in 2021, and so on. With harmonized safety standard, countries should be able to trade more as trade costs decrease. The coefficient of $D_{HA_{j,t}}$ is expected to be positive. We include two interaction terms of $\left(D_{HA_{j,t}} * D_{ASEAN_{i,j}}\right)$ and $\left(D_{HA_{j,t}} * D_{EU_{i,j}}\right)$ to capture a regional impact of safety standard harmonization. A positive sign of the coefficient of the interaction terms indicates a regional benefit from the regulatory convergence. That is, a rise in trade flows within the region exceeds that with the rest of the world.

All of main control variables listed in the traditional gravity model are included. Firstly, the effect of size factors (Y and E) are expected to be positive. Richer importing country j (demand) can consume more of medical devices from country i. Similarly, larger firms (or supply capacity) from exporting country i have more access to importing country j. Secondly, the effect of bilateral resistances should be negative on bilateral trade flow. The farther away the country pair is, the lower amount of bilateral trade flow between a country pair. Thus, the expected sign of the coefficient of *Dist* is negative. If a country pair shares the same formal language, has a colonial relationship, and has a common physical border, bilateral trade between a country pair should be higher. The expected signs for *Language, Colony* and *Contiguity* are positive. Thirdly, the effect of preferential trade agreements and trade liberalization between countries (*PTA*) is still inconclusive. The preferential trade agreement should facilitate the bilateral trade flows. Nonetheless, the actual result of trade agreement can vary due to the rules of origin and other administrative complications.

In addition, the time-varying *BOD* is incorporated into the model in accordance with Bergstrand *et al*. (2015) to account for all bilateral factors that affect international trade relative to intranational trade over time, on average, relative to the base period. Also, the approximation method of the MR term employed in this study are based on the first-order Taylor series expansion, as proposed by Baier and Bergstrand (2010). This approach is utilized to determine the exogenous actual MR, which aligns with the underlying theoretical framework.

6. Data Sources, Variable Construction, and Econometric Issues

We employ a panel dataset (*exporter-importer-product-time*) of medical device trade of 167 exporting countries' and 105 importing countries' flow from 1990 to 2022.[5] These countries are classified into developing and developed country groups, based on the United Nations country classification.[6]

The medical device import is classified at 6-digit-level Harmonized System code. We categorize medical devices into 4 groups: single-use medical device, reagent and test kits, implantable single-use medical device, and durable medical device.[7] The single-use medical devices, and reagent and test kits are considered to be of lower risk classification as they are not intended for internal use within the human body. Conversely, implantable single-use and durable medical devices are manufactured with greater complexity and are categorized as higher risk.

The construction of safety standard harmonization is represented as a dummy variable, with a value of 1 assigned to importing country *j* if there is an active attempt to align safety standards in medical equipment. The Regulation (EU) 2017/745 was passed by European Union member states in 2017, with its implementation date postponed until 2021, so granting member states a four-year period to make necessary adaptations. In the years 2021-2022, the dummy variable for harmonization of safety standards for the EU27 is projected to attain a value of 1. The ASEAN Medical Device Directive offers a comprehensive framework for member states to follow in the pursuit of harmonized regulations for medical devices. Each party has the authority to issue the instrument of ratification or finalize the harmonization process at their own discretion. Hence, the dummy variable for harmonization of safety standards for the ASEAN will exhibit variation among different countries. In addition, the size factors (Y and E) are measured by Gross Domestic Product (GDP) of importing and exporting countries.

The data are from several sources. The medical device imports are retrieved from S&P Global Market Intelligence. The GDP data are collected from World Bank database. The others gravity variables are from a Centre d'Etudes Prospectives et d'Informations Internationales (CEPII).

To cope with the presence of zero trade flows in gravity model, we follow Suanin (2023) by estimating the model in a multiplicative form as illustrated in the previous equation and using Poisson pseudo-maximum likelihood (PPML) method purposed by Silva and Tenreyro (2006). This method provides consistent, unbiased estimates and robust results against any

[5] See Appendix Tables A2 for details on the list of countries used the study.
[6] The list of developed and developing countries based on the U.N. country classification (2023 edition): https://desapublications.un.org/file/1113/download
[7] See Appendix Tables A1 for details on the data classification for 6-digit HS code for medical devices

heteroscedasticity patterns, even when there is a large proportion of zero trade flows (Yotov *et al*., 2016; Crivelli and Groschl, 2016).

Another concern in estimating the gravity model is the computation method of the MR terms. In the past literatures, importer-time and exporter-time fixed effects are used to compute MR terms since these fixed effects can capture the observable and unobservable country-time specific impacts (Olivero and Yotov, 2012; Baldwin and Taglioni, 2006; Rose and van Wincoop, 2001; Ferro *et al*., 2013; Shepherd and Wilson, 2013; and Crivelli and Groschl, 2016). Nevertheless, applying importer-time and exporter-time fixed effects cannot investigate the effects of time-varying independent variables related to exporting and importing countries. We then follow Baier and Bergstrand (2010) as the time-varying bilateral variable of interest, D_{HA}, is not omitted in the model.

7. Results

The estimated gravity equations are reported in table 5.[8] In column (1), the estimated result based on the entire sample indicates that safety standard harmonization (D_{HA}) has a positive impact on bilateral trade flows at the 0.05 significance level. An effort to harmonize safety standard is expected to raise bilateral trade flow by 29.69 percent.[9] All control variables are significant at small conventional levels, and almost all of them exhibit the expected signs based on theoretical expectations.

Considering the estimates at the product levels, we found that the coefficients of D_{HA} for trade on single-use, and implantable single-use medical devices are 0.53 and 0.40, respectively (columns (2) and (4) in Table 5). When importing countries adopt safety standard harmonization, trade flow for single-use medical devices is expected to increase by 69.89 percent and 49.18 percent for implantable single-use medical devices, respectively. However, according to columns (3) and (5), safety standard harmonization does not significantly promote the flow of trade in reagent and test kits, as well as durable medical devices. One plausible argument for regent and test kits is that, while their development requires a scientific foundation, their production replication becomes very simple once a sufficient body of testing knowledge is established. As a result, a decrease in trade costs as a result of safety standard harmonization has no effect on increasing trade flows. Also, importers of durable medical devices typically pay brand royalties to specific manufacturers.[10]

[8] The results are resistant to the endogeneity issue caused by the possible reverse causality of trade on the policy variable *PTA*. Based on the panel VAR model, the Granger causality test indicates that there is no Granger causality of *MD* on *PTA*.

[9] Baier and Bergstrand (2007) and Yotov *et al*. (2016) indicate that the trade effect of bilateral variable is equal to $[e^{\alpha} - 1] * 100$ percent, where α is the estimated coefficient.

[10] Donzé (2022) reports that 8 out of 10 largest medical device companies are from the US. Their reputation guarantees their quality, and thus purchasing medical devices from a reputable firm also signals their patients that they provide the best medical services.

Hence, the cost savings from standardization may be insufficient to facilitate bilateral trade in durable medical devices.

Table 5. The determinants of medical device trade

Importer: All	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	0.26***	0.53***	0.13	0.40**	0.16
	(0.08)	(0.10)	(0.09)	(0.19)	(0.10)
Log Y	1.03***	0.87***	0.87***	0.97***	1.07***
	(0.01)	(0.01)	(0.01)	(0.02)	(0.02)
Log E	0.99***	1.01***	1.17***	0.89***	0.99***
	(0.01)	(0.01)	(0.01)	(0.03)	(0.01)
Log Dist	-0.33***	-0.39***	-0.51***	-0.37***	-0.32***
	(0.02)	(0.02)	(0.02)	(0.03)	(0.02)
Contiguity	0.79***	0.76***	0.25***	0.21**	0.83***
	(0.05)	(0.06)	(0.04)	(0.10)	(0.06)
Language	-0.11**	-0.02	0.68***	0.81***	-0.21***
	(0.05)	(0.06)	(0.04)	(0.12)	(0.06)
Colony	0.34***	0.30***	0.36***	0.50***	0.30*
	(0.12)	(0.10)	(0.11)	(0.16)	(0.18)
PTA	0.80***	0.62***	0.39***	-0.25**	0.89***
	(0.03)	(0.04)	(0.04)	(0.10)	(0.04)
Constant	-38.78***	-35.93***	-40.68***	-39.18***	-39.41***
	(0.62)	(0.50)	(0.46)	(0.78)	(0.75)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.86	0.82	0.85	0.74	0.84
No. of obs.	1,891,681	473,041	472,913	472,518	472,857

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **, and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively.

Table 6 presents the estimated result when the importers are restricted only to ASEAN. We found that the AMDD has no significant effect on ASEAN medical device imports. At the product level, however, we noticed that the AMDD has an adverse effect on the importation of single-use medical devices into ASEAN. One possible argument is that single-use medical devices can be inexpensively replicated. The implementation of a safety standard harmonization agreement across nations will enable manufacturers in the importing country to effectively track the production process, replicate it, and engage in competition with imported goods. In addition, the sum of the coefficients (D_{HA}*D_{ASEAN} and D_{HA}) is significantly positive for ASEAN imports in reagent & test

kits, and implantable single-use medical devices. [11] In other words, the AMDD are able to promote regional trade flows within ASEAN in these types of medical devices.

Table 6. The determinants of medical device trade of ASEAN

Importer: ASEAN	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	-0.03	-0.32**	-0.01	0.16	0.06
	(0.11)	(0.13)	(0.16)	(0.16)	(0.14)
D_{HA}*D_{ASEAN}	0.25	0.30	1.15***	3.59***	0.12
	(0.23)	(0.19)	(0.29)	(0.39)	(0.34)
Log Y	0.94***	1.44***	1.13***	1.18***	0.76***
	(0.04)	(0.06)	(0.06)	(0.06)	(0.05)
Log E	1.09***	1.14***	1.19***	1.06***	1.06***
	(0.03)	(0.02)	(0.03)	(0.05)	(0.04)
Log Dist	-0.49***	-0.45***	-0.12	1.35***	-0.55***
	(0.05)	(0.06)	(0.07)	(0.12)	(0.06)
Contiguity	0.44*	1.39***	0.82***	0.69***	-0.07
	(0.24)	(0.17)	(0.31)	(0.26)	(0.28)
Language	-0.11	0.69***	0.44***	0.10	-0.47***
	(0.10)	(0.11)	(0.14)	(0.15)	(0.12)
Colony	-1.16***	-0.75***	-0.36	0.18	-1.35***
	(0.10)	(0.22)	(0.35)	(0.21)	(0.13)
PTA	0.73***	0.91***	0.58***	0.95***	0.72***
	(0.08)	(0.10)	(0.10)	(0.15)	(0.11)
Constant	-37.06***	-52.24***	-49.36***	-61.34***	-31.41***
	(1.69)	(1.69)	(2.09)	(2.39)	(2.16)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.79	0.87	0.81	0.76	0.76
No. of obs.	79,683	19,952	19,937	19,906	19,939

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **, and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively; based on the estimates in column (3) and (4), the null hypothesis that $\alpha_1 + \alpha_2 \leq 0$ is rejected at the 0.01 significance level

Table 7 restricts the importers to the EU27. According to the findings, harmonization of safety standards, as facilitated by Regulation (EU) 2017/745, has a positive impact on regional trade within the European Union for all medical product types. Meanwhile, standardization can facilitate EU imports from other countries worldwide in only three product groups: single-use, reagent & test kits, and implantable single-use medical devices (columns 2, 3, and 4, Table 7).

[11] When D_{ASEAN} = 1, a country pair is from ASEAN. $\alpha_1 + \alpha_2$ indicates the effect of the AMDD on trade flows between ASEAN countries.

Table 7. The determinants of medical device trade of EU

Importer: EU27	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	-0.31**	0.83***	0.50**	0.92***	-0.73***
	(0.12)	(0.20)	(0.20)	(0.34)	(0.15)
D_{HA} *D_{EU}	0.79***	0.76***	0.68***	0.65***	0.91***
	(0.09)	(0.14)	(0.13)	(0.25)	(0.12)
Log Y	0.83***	0.76***	0.87***	1.05***	0.83***
	(0.01)	(0.01)	(0.02)	(0.03)	(0.01)
Log E	0.99***	0.91***	1.29***	1.02***	0.99***
	(0.01)	(0.01)	(0.02)	(0.03)	(0.01)
Log Dist	-0.47***	-0.56***	-0.67***	-0.61***	-0.43***
	(0.02)	(0.02)	(0.03)	(0.04)	(0.02)
Contiguity	0.45***	0.37***	0.32***	0.22**	0.48***
	(0.06)	(0.05)	(0.05)	(0.09)	(0.07)
Language	0.34***	0.37***	0.56***	0.95***	0.29***
	(0.05)	(0.06)	(0.06)	(0.11)	(0.07)
Colony	0.23	0.14	1.84***	-0.32	-0.05
	(0.15)	(0.13)	(0.36)	(0.36)	(0.21)
PTA	1.48***	0.58***	1.27***	0.17	1.68***
	(0.06)	(0.08)	(0.08)	(0.14)	(0.08)
Constant	-28.46***	-25.39***	-38.54***	-37.74***	-28.08***
	(0.47)	(0.58)	(0.72)	(1.38)	(0.58)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.84	0.77	0.85	0.70	0.83
No. of obs.	351,930	87,945	87,944	87,938	88,006

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **. and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively; the null hypothesis that $\alpha_1 + \alpha_3 \leq 0$ is rejected at the 0.01 significance level.

Comparing the results of ASEAN and EU27 cases (Tables 6 and 7), we observe that the AMDD promotes the trade of medical devices within ASEAN but mostly has no effect on trade with the rest of the world. On the other hand, Regulation (EU) 2017/745 promotes trade flows between EU27 member states and the rest of the world (except durable ones). The potential cause could be attributed to the disparities between directive and regulatory agreements. Since if a medical device that has obtained registration in an EU member state is eligible for marketing in all other EU member states, thus the Regulation (EU) 2017/745 successfully lower the information, specification, and conformity assessment costs. AMDD, on the other hand, cannot comparatively lessen trade costs as much as EU because a medical device registered in an ASEAN member state

is not permitted to be marketed in other ASEAN member states. Therefore, the benefits enjoyed by medical device firms entering EU and ASEAN are vastly different.

A robustness check is performed to examine the impact of safety standard harmonization during the COVID-19 pandemic[12], as reported in Table 8. The finding indicates that harmonization has a significantly positive impact on global trade in single-use medical devices and implantable single-use devices. The utilization of single-use medical devices, such as face masks and personal protective equipment, is critical for the prevention of pandemics. In this regard, the harmonization of safety standards plays a key role in promoting trade flows and ensuring that patients and users have unhindered access to essential medical devices.

Table 8. The determinants of medical device trade during the COVID-19 periods

Importer: All	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	0.07	0.48***	0.14	0.57***	-0.07
	(0.08)	(0.10)	(0.09)	(0.18)	(0.10)
Log Y	1.00***	0.87***	0.91***	0.99***	1.04***
	(0.03)	(0.03)	(0.02)	(0.05)	(0.04)
Log E	0.96***	0.98***	1.16***	0.83***	0.95***
	(0.02)	(0.03)	(0.03)	(0.05)	(0.03)
Log Dist	-0.23***	-0.40***	-0.40***	-0.43***	-0.17***
	(0.04)	(0.05)	(0.05)	(0.08)	(0.05)
Contiguity	0.99***	0.77***	0.29**	-0.10	1.15***
	(0.18)	(0.17)	(0.12)	(0.30)	(0.21)
Language	-0.17	-0.24	0.62***	0.81**	-0.30
	(0.16)	(0.18)	(0.13)	(0.34)	(0.19)
Colony	0.41**	0.32	0.33	0.43	0.41*
	(0.16)	(0.28)	(0.24)	(0.35)	(0.22)
PTA	0.67***	0.69***	0.37***	-0.15	0.74***
	(0.10)	(0.09)	(0.11)	(0.25)	(0.13)
Constant	-38.24***	-35.34***	-42.33***	-38.55***	-39.09***
	(1.34)	(1.49)	(1.24)	(1.70)	(1.76)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.82	0.81	0.82	0.68	0.82
No. of obs.	174,155	43,589	43,500	43,495	43,571

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **, and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively.

[12] In this study, the COVID-19 pandemic covers the period 2020-2022.

Following that, we look at the regional benefits of safety standard harmonization during the COVID-19 periods (Tables 9 and 10). The positive magnitude of the sum of the coefficients (the interaction term and D_{HA}) indicates that harmonization of safety standards significantly promotes trade flows within each region (ASEAN and EU) for all types of medical devices, with the exception of durable ones. In other words, medical device security within the ASEAN region is achieved through harmonization efforts during public health crises. Similarly, Regulation (EU) 2017/745 also promotes intra-EU medical device trade. Nevertheless, the standard harmonization is still ineffective in promoting durable medical device security in both regions.

Table 9. The determinants of medical device trade of ASEAN during the COVID-19 period

Importer: ASEAN	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	0.06	-0.06	0.21	-0.41	0.22
	(0.22)	(0.15)	(0.31)	(0.35)	(0.35)
D_{HA} *D_{ASEAN}	1.31**	1.35***	1.72**	3.15***	1.22
	(0.54)	(0.32)	(0.72)	(0.62)	(0.83)
Log Y	0.59***	0.88***	0.67***	1.24***	0.38***
	(0.08)	(0.09)	(0.18)	(0.14)	(0.11)
Log E	1.06***	1.14***	1.30***	0.95***	0.97***
	(0.05)	(0.05)	(0.08)	(0.10)	(0.07)
Log Dist	0.00	0.21	-0.11	1.44***	-0.13
	(0.22)	(0.13)	(0.30)	(0.30)	(0.35)
Contiguity	0.66*	1.44***	0.60	0.17	-0.15
	(0.35)	(0.22)	(0.54)	(0.48)	(0.44)
Language	0.14	0.23	0.72**	0.14	0.03
	(0.16)	(0.16)	(0.34)	(0.26)	(0.26)
Colony	-0.26	-0.58*	0.69	-0.99**	-0.47
	(0.39)	(0.33)	(0.88)	(0.42)	(0.53)
PTA	1.54***	1.93***	0.95***	1.21***	1.52***
	(0.19)	(0.16)	(0.35)	(0.34)	(0.26)
Constant	-29.62***	-41.19***	-42.82***	-60.43***	-21.28***
	(2.76)	(2.77)	(5.55)	(4.56)	(3.65)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.84	0.93	0.83	0.71	0.80
No. of obs.	8,878	2,244	2,204	2,200	2,230

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **, and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively; based on the estimates in columns (1) to (4), the null hypothesis that $\alpha_1 + \alpha_2 \leq 0$ is rejected at the 0.01 significance level.

Table 10. The determinants of medical device trade of European Union during the COVID-19 period

Importer: EU27	(1) All	(2) Single use	(3) Reagent & Test kit	(4) Implantable single use	(5) Durable
D_{HA}	-0.72***	-0.47***	-0.72***	-0.30	-0.86***
	(0.10)	(0.15)	(0.14)	(0.30)	(0.14)
D_{HA} *D_{EU}	0.83***	0.79***	1.01***	0.71**	0.86***
	(0.10)	(0.17)	(0.14)	(0.31)	(0.13)
Log Y	0.90***	0.88***	1.04***	1.12***	0.88***
	(0.03)	(0.04)	(0.05)	(0.08)	(0.04)
Log E	0.96***	0.91***	1.39***	1.02***	0.92***
	(0.03)	(0.03)	(0.04)	(0.07)	(0.04)
Log Dist	-0.51***	-0.64***	-0.64***	-0.93***	-0.42***
	(0.05)	(0.07)	(0.08)	(0.13)	(0.06)
Contiguity	0.20	0.14	0.06	-0.25	0.24
	(0.14)	(0.13)	(0.16)	(0.24)	(0.18)
Language	0.34**	0.29	0.82***	0.84***	0.26
	(0.13)	(0.18)	(0.18)	(0.26)	(0.17)
Colony	0.06	-0.15	2.27***	0.14	-0.91**
	(0.35)	(0.33)	(0.75)	(1.06)	(0.36)
PTA	0.39**	-0.24	0.21	-0.33	0.67***
	(0.16)	(0.18)	(0.20)	(0.36)	(0.22)
Constant	-28.77***	-26.47***	-45.12***	-36.51***	-27.60***
	(1.08)	(1.49)	(1.92)	(3.72)	(1.58)
BOD	yes	yes	yes	yes	yes
MR	yes	yes	yes	yes	yes
Time FE	yes	yes	yes	yes	yes
Product FE	yes				
Pseudo R^2	0.82	0.76	0.85	0.67	0.83
No. of obs.	40,289	10,076	10,044	10,067	10,102

Note: The standard errors are clustered by product categories and shown in parentheses; ***, **, and * are statistically significant at 0.01, 0.05 and 0.1 levels, respectively; based on the estimates in columns (1) to (4), the null hypothesis that $\alpha_1 + \alpha_3 \leq 0$ is rejected at the 0.01 significance level.

8. Concluding Remarks

The implementation of a global initiative to harmonize safety standards would be advantageous in addressing the challenges posed by a global pandemic. These endeavors, however, require significant time and effort from all parties involved in the negotiation process, and as a result, the impact of these efforts is yet to be determined. Our focus is then on analyzing the influence of safety standard harmonization on regional trade. We selected Regulation (EU) 2017/745 and the ASEAN Medical Device Directive (AMDD) as case studies. A compelling narrative may serve as evidence to reinforce the global taskforce's confidence and affirm their alignment with the correct

course of action. With the successful implementation of these initiatives, the achievement of regional or even worldwide medical device security appears to be a plausible future.

This article demonstrates that the harmonization of safety standards in the EU has a positive impact on trade flows, both within the region and with other countries globally. The AMDD exhibits limitations in facilitating trade flows from non-regional nations, while effectively encouraging intra-regional trade flows. Although the benefits derived from safety standard harmonization agreements by EU and ASEAN are different, both accords contribute to the regional medical device security during the time of public health crisis.

The presence of regulatory heterogeneity across trading partners gives rise to prevalent costs associated with information, specification, and conformity assessment. The implementation of EU medical device regulation has effectively addressed regional regulatory disparities and effectively reduced trade costs. Conversely, the AMDD has not demonstrated the same ability to mitigate trade costs. To enhance the medical device security in ASEAN, a revised agreement is needed to facilitate a more comprehensive safety standard harmonization, akin to the measures devised by the European Union.

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Appendix

Table A1 Classifications on Medical Devices

Category	HS2002
Single-use	300510, 300590, 300610, 300640, 300670, 300691, 330620, 340700, 370110, 370210, 370232, 370239, 370241, 370242, 370243, 370244, 370251, 370252, 370253, 370254, 370255, 370256, 370291, 370292, 370293, 370294, 370295, 370296, 370297, 370298, 370400, 370500, 370510, 370520, 370590, 392620, 392690, 401511, 901831, 901832, 901839, 401512
Reagents and Test kits	300620, 300630, 320810, 320820, 320890, 382200, 382211, 382212, 382213, 382219
Implantable Single-use	902100, 902110, 902111, 902119, 902121, 902129, 902130, 902131, 902139
Durable	300650, 761520, 841850, 841920, 842129, 842310, 870322, 870323, 870324 870331, 870332, 870333, 870390, 870600, 870710, 871310, 871390, 871420, 900000, 900100, 900200, 900300, 900400, 900500, 900600, 900630, 900700, 900800, 900900, 901000, 901100, 901110, 901120, 901180, 901190, 901200, 901300, 901310, 901500, 901700, 901800, 901811, 901812, 901813, 901814, 901819, 901820, 901841, 901849, 901850, 901890, 901900, 901910, 901920, 902000, 902140, 902150, 902190, 902200, 902211, 902212, 902213, 902214, 902219, 902221, 902230, 902290, 902300, 902500, 902600, 902630, 902700, 902900, 903000, 903100, 903200, 940210, 940290, 940510, 940520, 940540, 940591, 940592

Table A2 The list of importing and exporting countries

Importing countries:
Albania, Algeria, Angola, Argentina, Australia, Austria, Azerbaijan, Bahrain, Belarus, Belgium, Belize, Bolivia, Botswana, Brazil, Brunei, Bulgaria, Canada, Chile, China, Colombia, Congo, Costa, Cyprus, Czechia, Côte d'Ivoire, Denmark, Dominican, Ecuador, Egypt, El Salvador, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Honduras, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Korea, Kuwait, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Macao, Malaysia, Malta, Mauritius, Mexico, Morocco, Mozambique, Namibia, Netherlands, New Zealand, Nicaragua, Nigeria, Norway, Pakistan, Panama, Paraguay, Peru, the Philippines, Poland, Portugal, Puerto Rico, Qatar, Republic of North Macedonia, Romania, Russian, Rwanda, Senegal, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tanzania, Thailand, Togo, Tunisia, Turkey, Ukraine, UK, USA, Uruguay, Uzbekistan, Vietnam, Zambia, Zimbabwe
Exporting countries:
Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bermuda, Bolivia, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Canada, Chad, Chile, China, Colombia, Comoros, Democratic Republic of the Congo, Congo, Costa Rica, Cyprus, Czechia, Côte d'Ivoire, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Eswatini, Ethiopia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, India, Indonesia, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Korea, Kuwait, Kyrgyzstan, Lao, Latvia, Lesotho, Libya, Lithuania, Luxembourg, Macao, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Republic of North Macedonia, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Sudan, Suriname, Sweden, Switzerland, Tajikistan, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Tuvalu, Uganda, Ukraine, United Arab Emirates, UK, USA, Uruguay, Uzbekistan, Vanuatu, Viet Nam, Zambia, Zimbabwe