



KMDIA



Korea Medical Devices
Industry Association

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Chairman's Message

Since its establishment in 1999, Korea Medical Devices Industry Association(KMDIA) have led the effort to supply high-quality medical devices and to advance the new technologies, as we work together with healthcare regulatory authorities and other medical industry associations.

Based on the past experience, we have grown to create the innovative medical devices with ICT, AI, IVD and Robotics etc. along the 4th industrial revolution trends responding quickly to the pandemic and other healthcare issues.

Most recently, Korean medical device industry has shown the competitiveness to the world with the new growth industry engine known as 'K-medical devices'.

As a chairman of KMDIA, I will continue to work closely with the government to promote and support the medical devices industry to become the center of 3 major bio-health industry.

In the era of the 4th industrial revolution, medical devices industry is rapidly developing and quickly transferring to digital healthcare. We reconfirmed how important medical devices are, especially when it comes to tackle the pandemic such as COVID-19 and also witnessed the meaningful cooperation throughout the medical devices industry.

KMDIA will strengthen the interactive communication and make the opportunities with the global trends in the post COVID-19 era.

Thank you.

Korea Medical Devices Industry Association

Chairman *Cheolwook Yoo* 



About KMDIA

The Better KMDIA for a Better Medical Devices Industry

The Korea Medical Devices Industry Association(KMDIA) is a trade association that leads advocacy rights of the medical devices industry and contributes to enhancing global competitiveness of member companies.

Since its foundation in 1999, KMDIA represents over 1,076 member companies including manufacturers, importers, suppliers and other stakeholders etc. and they account for more than 80% of Korean medical devices industry.

We dedicate ourselves to be the trustworthy partner for the future growth of Korean medical device industry.

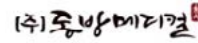
Mission

Our mission is to develop medical device industry and to advance innovative medical technologies with the voice of Korean companies and key stakeholders.

- 1/ Establishing fundamental infrastructure for the growth of medical device industry
- 2/ Shaping regulatory policy for the medical device industry
- 3/ Facilitating collaboration within the medical device industry
- 4/ Supporting continued medical device export growth
- 5/ Establishing a fair supply system of medical device
- 6/ Promoting regulatory harmonization in collaboration with global associations

Board of Directors









































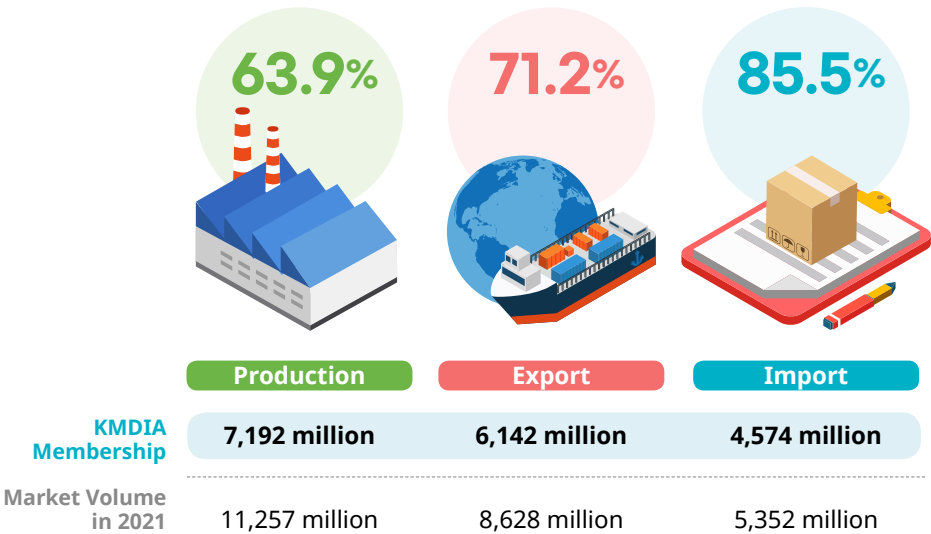
Membership

(As of 30th May, 2023)

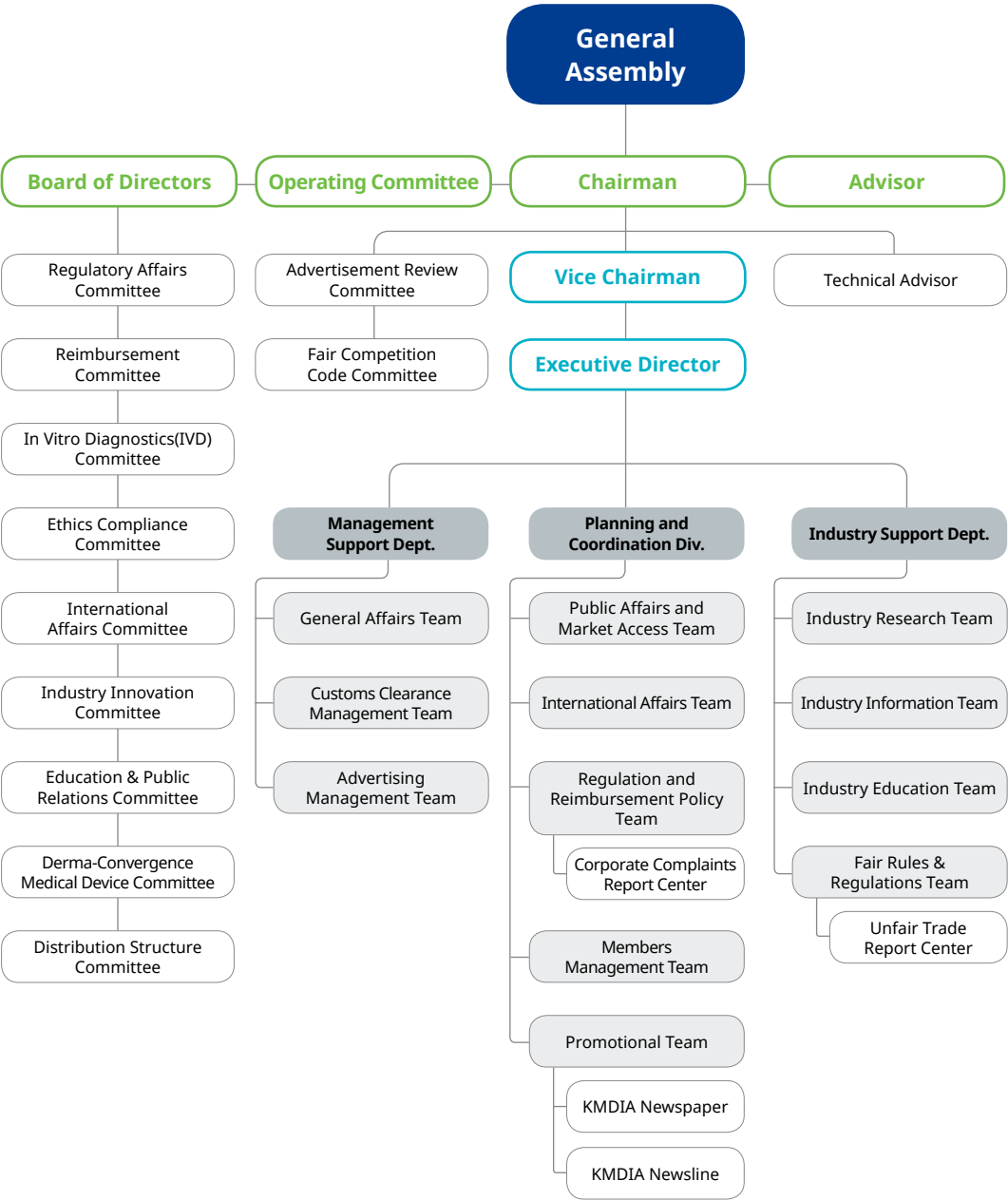


Membership’s market share in Korea

(Unit : US\$ million) (2021)



Organization



Our Work

01

Regulatory Affairs & Reimbursement



- Promoting regulatory convergence in collaboration with government, member companies and other key stakeholders
 - Suggesting industries' opinions regarding legislative/administrative guidelines
- Advocacy activities for overall market access including health policy, Health Technology Assessment (HTA), coverage, coding and payment
- Positioned as the main medtech industry stakeholders to the health authorities;
 - Ministry of Health and Welfare (MoHW)
 - Health Insurance Review and Assessment Service (HIRA)
 - National Evidence-based healthcare Collaborating Agency (NECA)
 - National Health Insurance Service (NHIS)

02

Membership Benefits



- Training and Education for Human Resources
 - Fostering medical device professionals through practical education programs*
* (e.g. RAs, Reimbursement, Medical Device Marketing, ISO13485, and etc.)
- Reflecting Voice of Member Companies
 - Stating industry's opinion of the current issues by working in close collaboration with member companies
- Conducting Seminars & Events
 - Providing timely information on facing key issues and medical device market trends

03

Public Relations

- Disseminating the latest news and information through the KMDIA marketing channels; Newspaper, Newline(Online), Newsletter etc.
- Covering the industry's perspectives on major healthcare issues
- CSR(Corporate Social Responsibility)
 - Free Health Examination Service for the vulnerable
 - Medical Device Donation and Medical Volunteering Activities

04

Research in Policy of Medical Device Industry

- Publishing a white paper of Korean medical device industry
- Publishing regularly an analysis report on Korean/overseas medical device market and policies
- Conducting research service tasks assigned by the government and institutions

05

Government Assigned Business

- Issuing Annual Statistic Report* on Korean medical devices market
** Mandatory report from all Korean medical device companies on the production, exports, imports and repairs.*
- Approving the Request of Standardized Customs Clearance Forecast Report on medical device in order to ensure the safe imports
- Approving application for Import Requirements Waiver
 - ※ In case of import for specific purposes of use (e.g. sample, clinical test, and etc.)
- Pre-reviewing medical devices advertisement
 - Enhancing the appropriate use of medical device by pre-reviewing false and exaggerated advertisement based on the Medical Devices Act.

06

Legals, Ethics and Compliance

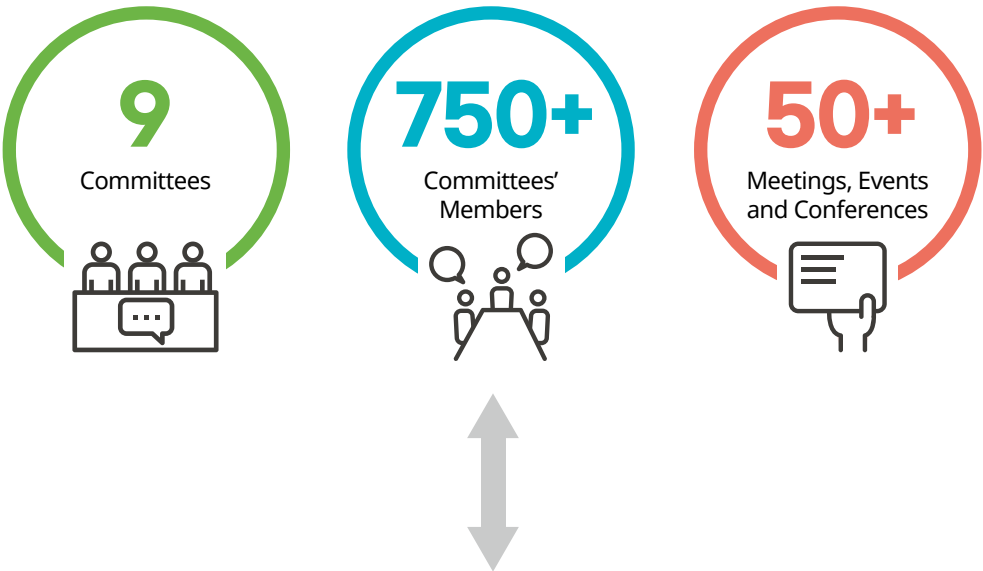
- Implementing Fair Competition Code(Voluntary Industry Code) of medical device to ensure public order of fair competition in the distribution of medical device
- Holding regularly Independent Review Panel Meeting
 - Reviewing commercial rebates such as product seminars, product training, sponsorship, souvenirs, honorarium etc.

07

International Cooperation and Exchange

- Organizing Korean pavilion in overseas medical device exhibitions operating government funds by Ministry of Trade, Industry and Energy(MOTIE) and Ministry of SMEs and Startups(MSS)
- Enhancing international cooperation by working with overseas medical device industry associations
- Operating KMDIA's Business Match-making Platform for the medical device industry (*seeKOREA : <http://global.kmdia.or.kr>)
- Supporting Global Regulatory Harmonization
 - Operating IMDRF office of Korea in collaboration with Ministry of Food and Drug Safety(MFDS)
- Co-hosting K-Med Expo in Vietnam(Hochiminh City)

Committees



① Regulatory Affairs Committee

② Reimbursement Committee

③ In Vitro Diagnostics(IVD) Committee

④ Ethics Compliance Committee

⑤ Industry Innovation Committee

⑥ International Affairs Committee

⑦ Education & Public Relations Committee

⑧ Derma-Convergence Medical Device Committee

⑨ Distribution Structure Committee

Fair Competition Code in Korea

Purpose

- Ensure public order of fair competition in the distribution of Medical Devices
- Maintain and improve public health by curbing unfair customer solicitation

Relevant Law

- **Fair Trade Act**

Prohibition of Unfair Trading(Unfair Solicitation of Customers)

- **Medical Devices Act**

Dual Punishment Provision(7 safe harbors for provision of economic profit)

Substantive

- Provision of Samples
- Donations to Medical Institutions
- Sponsorship of Hosting and Operating Academic Conferences
- Sponsorship of HCP participation in Academic Conferences
- Product Seminar
- Product Training
- Lectures and Consultations
- Clinical Trial Sponsorship
- Market Survey
- Post-marketing Survey
- Advertisements and Exhibitions

Process

- Composition and operation of Fair Competition Code Review Committee
- Investigation of Code Violations
- Sanctions against Code Violations
- Member companies' duty to cooperate
- Record keeping by KMDIA
- Appeals against sanctions
- Pre-review and Post-report requirements are articulated in each item

Examples of Monetary Limits

Meals



- **Product seminars / Product Training :**
within KRW 100,000(USD 85) / meal(VAT and service fee exc. refreshments incl.)
- **Product seminar for single medical institution :**
within KRW 100,000(USD 85)/ day, up to 4 times/month

Lodging



- **Sponsorship for participants :**
up to KRW 200,000(USD 170)/night (Domestic); up to KRW 350,000(USD 280) / night(Overseas) (VAT incl.)
- **Product seminars :**
Same as above

Souvenirs,
Promotional Gifts



- **Souvenirs :**
within KRW 50,000(USD 43) (multiple medical institutions)
- **Promotional gifts :**
within KRW 10,000(USD 8.5) (single medical institution)



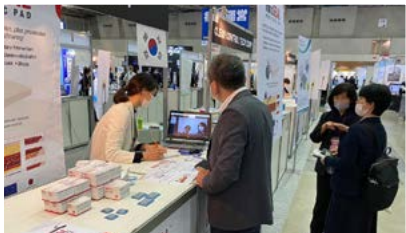
Exhibitions in 2023

In Korea

Exhibition Name	Date	Venue
KIMES Seoul	2023. 3. 23 ~ 26	COEX
KOAMEX Daegu	2023. 6. 30 ~ 7. 2	EXCO
KIMES Busan	2023. 10. 13 ~ 15	BEXCO

International (Korean Pavilion)

Exhibition Name	Date	Venue
K-Med Expo Vietnam	2023. 06. 15 ~ 17	SECC, Hochiminh, Vietnam
Radiological Society of North America(RSNA)	2023. 11. 26 ~ 30	McCormick Place, Chicago, USA
Medical Japan Osaka	2024. 2	INTEX Osaka, Japan
Radiological Society of North America(RSNA)	2024. 11	McCormick Place, Chicago, USA



Global Networks



KMDIA PR Channels

KMDIA runs three different PR channels including Newspaper, Newline and Newsletter. According to your needs and preferences, you can advertise your company/product/service targeting potential clients who are involved in the medical industry. Use the channels to be promoted in the Korean market!

Newspaper

Monthly distributed to over 5,200 medical device companies, medical institutions, government agencies and relative organizations

(Unit : won)

Type	Page Number	Cost	Size (mm, width x height)	Remarks
1/3	1	900,000	240 x 102	All colored necessary
	Any other page	450,000		
Full page	2	1,200,000	240 x 340	
	23			
	24(last page)	1,500,000		
	Any other page	800,000		

Newline & Newsletter

- **Newline(www.kmdianews.com)** : online news portal posting latest issues, regulations, information in the medical device industry updated everyday

- **Newsletter** : e-mail newsletter distributed to over 12,000 receivers twice a week

(Unit : won)

Type	Newline	Newsletter
Cost	1,000,000/per month	250,000(one time)

- Size and placement negotiable
- 250 x 250(pixel) recommended

Advertisement Inquiry



paper@kmdia.or.kr / kmdia@kmdia.or.kr

Korean Medical Device Market in Number

Overview of Korean Medical Devices Market

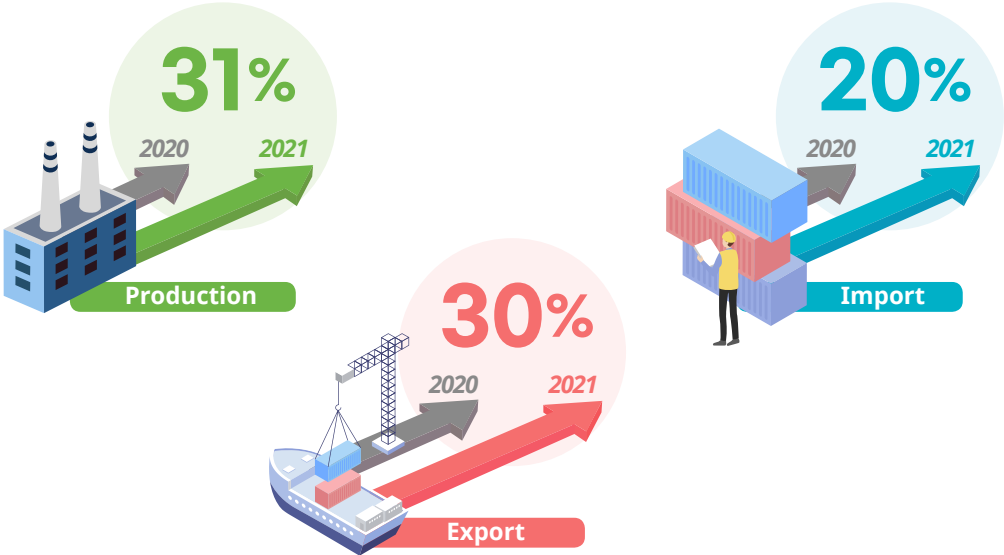
(Unit : US\$ million)

Classification	2019	2020	2021
Market size	6,695	6,383	7,981
Production	6,245	8,589	11,257
Exports	3,710	6,636	8,628
Imports	4,160	4,430	5,352

* Exchange rate : \$ = 1,165.65(2019), 1,180.05(2020), 1,144.42(2021)

* Market size = Production - Export + Import

* Source : Annual Statistic Report on Korean medical device market(Production, Export and Import), KMDIA



Top 10 Products in 2021

(Unit : US\$ million)

No.	Products	Amount	%
1	IVD reagents for infectious disease marker (immunological method)	1,758	15.62
2	Implant Fixture(endosseous)	1,262	11.21
3	IVD reagents for infectious disease marker (molecular diagnostics)	1,007	8.95
4	Ultrasound imaging system	497	4.42
5	Implant superstructure(endosseous)	482	4.28
6	Biomaterial graft / prosthesis	263	2.34
7	IVD reagent for infectious disease, Immunological method	239	2.13
8	IVD reagents for extracting nucleic acids	202	1.8
9	Soft contact lens(daily-wear)	188	1.68
10	Implant hand instrument(endosseous)	182	1.62

Top 10 Exports in 2021

(Unit : US\$ million)

No.	Products	Amount	%
1	IVD reagents for infectious disease marker (immunological method)	2,316	30.72
2	IVD reagents for infectious disease marker (molecular diagnostics)	800	10.61
3	Ultrasound imaging system	429	5.7
4	IVD reagent for infectious disease, Immunological method	368	4.89
5	Implant Fixture(endosseous)	316	4.2
6	Biomaterial graft / prosthesis	228	3.04
7	IVD reagents for extracting nucleic acids	164	2.19
8	Soft contact lens(daily-wear)	162	2.15
9	Implant superstructure(endosseous)	137	1.83
10	IVD strip for glucose self test	132	1.76

Top 10 Imports in 2021

(Unit : US\$ million)

No.	Products	Amount	%
1	Tool for specimens	357	7.64
2	Multifocal intraocular lens	195	4.18
3	Sumitomo Proton Therapy System	117	2.5
4	Soft contact lens(daily-wear)	113	2.42
5	Dialyser	79	1.7
6	Drug Eluting Stent, DES for Coronary Artery	75	1.62
7	Examination Gloves	75	1.62
8	Sight corrective ophthalmiclens	68	1.47
9	Hand-controlled electrode(single use)	63	1.37
10	CT system	58	1.24

Top 10 Export & Import Countries

Export

(Unit : US\$ million)

No.	Country	Amount	%
1	Germany	1,308	17.36
2	USA	707	9.39
3	China	620	8.23
4	Vietnam	436	5.79
5	Singapore	290	3.86
6	Italy	281	3.8
7	Russia	247	3.28
8	Japan	243	3.23
9	Netherlands	234	3.11
10	India	156	2.08

Import

(Unit : US\$ million)

No.	Country	Amount	%
1	USA	1,934	41.36
2	Germany	691	14.79
3	China	575	12.29
4	Japan	446	9.54
5	Switzerland	176	3.78
6	UK	77	1.67
7	France	72	1.54
8	Ireland	54	1.16
9	Italy	53	1.15
10	Taiwan	52	1.11

Export & Import Products by Continent

Export

(2021)

● America

1. IVD reagents for infectious disease marker (immunological method)
2. IVD reagents for infectious disease marker (molecular diagnostics)
3. Ultrasound imaging system

● East Europe

1. IVD reagents for infectious disease marker (immunological method)
2. Implant Fixture(endosseous)
3. Ultrasound imaging system

● West Europe

1. IVD reagents for infectious disease marker (immunological method)
2. IVD reagents for infectious disease marker (molecular diagnostics)
3. IVD reagent for infectious disease, Immunological method

● Middle East

1. IVD reagents for infectious disease marker (molecular diagnostics)
2. IVD reagents for infectious disease marker (immunological method)
3. Soft contact lens(daily-wear)

● Asia Pacific

1. IVD reagents for infectious disease marker (immunological method)
2. IVD reagents for infectious disease marker (molecular diagnostics)
3. Implant Fixture(endosseous)

● Africa

1. IVD reagents for infectious disease marker (immunological method)
2. IVD reagents for infectious disease marker (molecular diagnostics)
3. IVD reagents for diagnosis of HIV, HBV, HCV, HTLV

Import

(2021)

● America

1. Multifocal intraocular lens
2. Soft contact lens(daily-wear)
3. Drug Eluting Stent, DES for Coronary Artery

● East Europe

1. Suction system(line-powered)
2. Nd:YAG surgical laser
3. Radiofrequency heater

● West Europe

1. Dialyser
2. High permeability hemodialysis system
3. Multifocal intraocular lens

● Middle East

1. Electrosurgical system(general-purpose)
2. High Intensity Focused Ultrasound
3. Intense pulsed light

● Asia Pacific

1. Tool for specimens
2. Sumitomo Proton Therapy System
3. Examination Gloves

● Africa

1. Combination stimulator(class 2)
2. Suction system(manually-operated)
3. Occlusive dressing(hydrogel)

Looking for a Business Partner?

seeKOREA is here for you!

Start with seeKOREA to build your business!
Korea Medical Devices Industry Association (KMDIA) launches
business matching platform to support your business.

WHY seeKOREA?

- ✓ Searching for reliable suppliers & buyers
- ✓ Accessing to database of buying offers and demands
- ✓ Promoting your products to your target markets



How to register

- 1 Access to website
- 2 Upon your purpose to use seeKOREA, choose Seller or Buyer



Seller

To register company introduction & products



Buyer

To search for manufacturers & products



Please scan me for a
registration manual

Inquiries

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