

# JAPANESE INDUSTRY'S ACTIVITIES IN BRAZIL

**2018 DECEMBER 3**

**JAPAN EXTERNAL TRADE ORGANIZATION (JETRO)**

**SAO PAULO OFFICE**

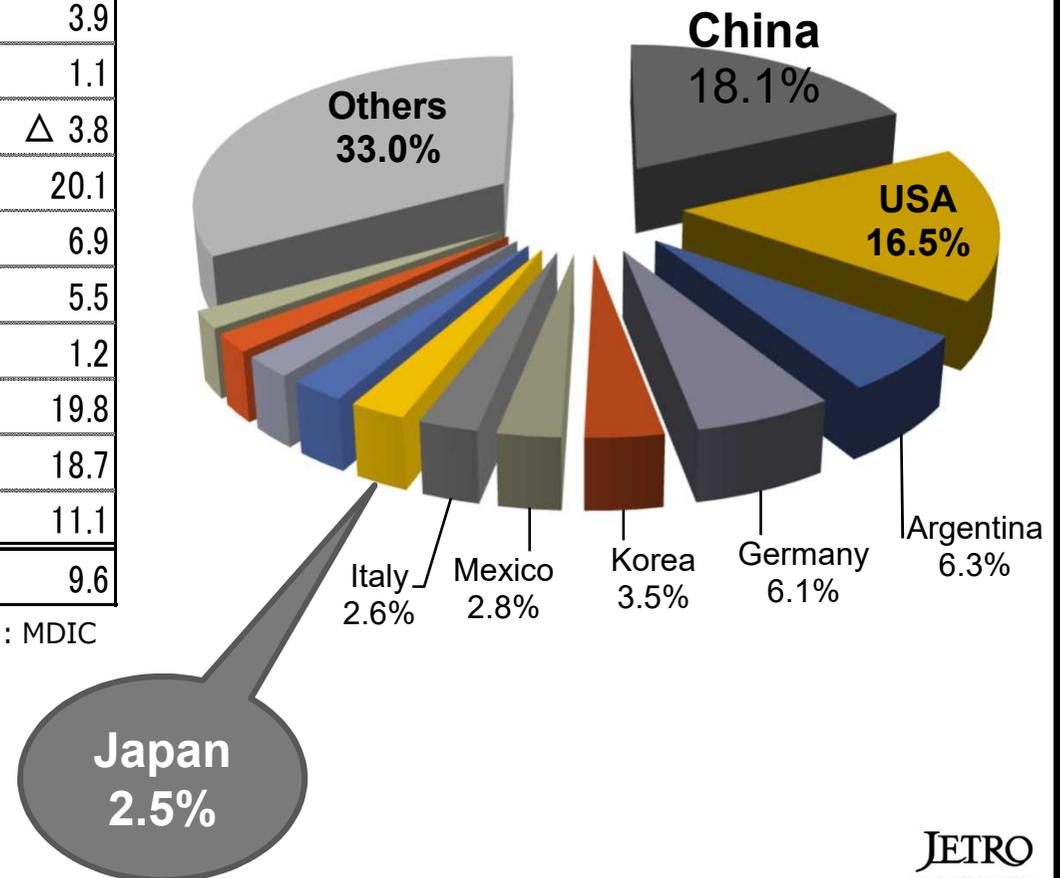
# Brazil's Top Import Partners

(Units: US\$ FOB million)

	2016	2017		
	Value	Value	Share	Growth Rate
China	23,364	27,321	18.1	16.9
USA	23,803	24,847	16.5	4.4
Argentina	9,084	9,435	6.3	3.9
Germany	9,131	9,227	6.1	1.1
Korea	5,449	5,240	3.5	△ 3.8
Mexico	3,528	4,238	2.8	20.1
Italy	3,703	3,958	2.6	6.9
<b>Japan</b>	<b>3,566</b>	<b>3,763</b>	<b>2.5</b>	5.5
France	3,679	3,723	2.5	1.2
Chile	2,882	3,453	2.3	19.8
India	2,483	2,946	2.0	18.7
Spain	2,565	2,851	1.9	11.1
Total	137,552	150,749	100.0	9.6

Source : MDIC

## The 8th largest exporter

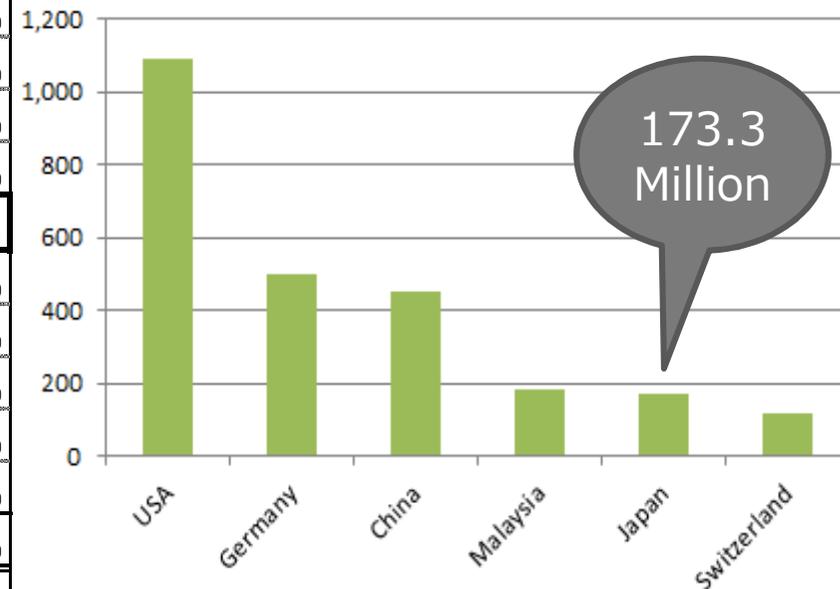


# Medical device Imports by Country of Origin

(Units: US\$ FOB million)

	2016	2017	
	Value	Value	Share
USA	1,130	1,092	29.0%
Germany	463	501	13.3%
China	355	452	12.0%
Malaysia	162	181	4.8%
<b>Japan</b>	<b>162</b>	<b>173</b>	<b>4.6%</b>
Switzerland	119	117	3.1%
France	108	117	3.1%
Korea	117	112	3.0%
Ireland	111	93	2.5%
UK	71	88	2.3%
Others	753		0.0%
<b>Total</b>	<b>3,551</b>	<b>3,771</b>	<b>100.0%</b>

## Imports by Country of Origin (2017)



Japan is the 5<sup>th</sup> largest exporter

# Medical device Imports from Japan

(Units: US\$ FOB million)

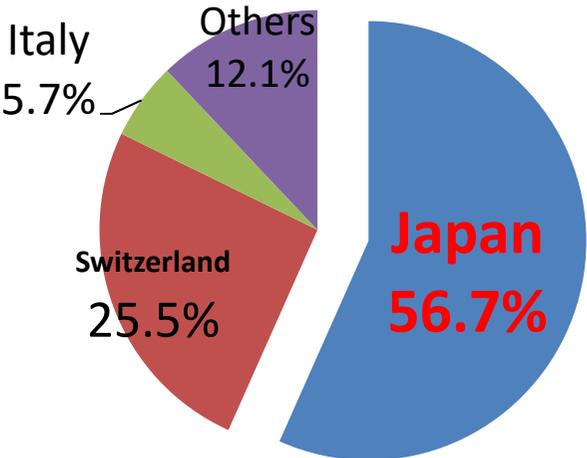
Description	2014	2015	2016	2017		Annual Average Growth Rate
	Value	Value	Value	Value	Share	
<b>Instruments and appliances used in medical, surgical, dental or veterinary sciences</b>	<b>76.7</b>	<b>68.6</b>	<b>58.9</b>	<b>72.8</b>	<b>61.4%</b>	<b>-1.7%</b>
<b>Other diagnostic equipment</b>	<b>34.6</b>	<b>22.2</b>	<b>16.8</b>	<b>22.2</b>	<b>18.7%</b>	<b>-13.8%</b>
<b>Other instruments and appliances(901890)</b>	<b>9.6</b>	<b>13.1</b>	<b>11.9</b>	<b>15.3</b>	<b>12.9%</b>	<b>16.9%</b>
Ultrasonic scanning apparatus	13.7	9.5	5.2	8.5	7.1%	-14.9%
Other syringes, needles, catheters, cannulae and the like	7.8	6.3	6.2	8.4	7.0%	2.3%
<b>Dental drill engines</b>	<b>2.6</b>	<b>2.9</b>	<b>6.0</b>	<b>5.6</b>	<b>4.7%</b>	<b>28.9%</b>
<b>Apparatus based on the use of X-rays or of alpha, beta or gamma radiations</b>	<b>42.4</b>	<b>27.5</b>	<b>29.2</b>	<b>27.0</b>	<b>22.8%</b>	<b>-14.0%</b>
<b>Computed tomography apparatus</b>	<b>21.7</b>	<b>13.0</b>	<b>11.2</b>	<b>13.1</b>	<b>11.1%</b>	<b>-15.4%</b>
Other, including parts and accessories	5.0	3.7	7.1	4.3	3.7%	-4.6%
For other uses	6.5	4.9	4.9	3.8	3.2%	-16.0%
<b>Photographic plates and film in the flat for X-ray</b>	<b>20.2</b>	<b>13.7</b>	<b>10.8</b>	<b>10.5</b>	<b>8.9%</b>	<b>-19.6%</b>
<b>Wadding, gauze, bandages and similar articles</b>	<b>4.8</b>	<b>5.9</b>	<b>2.5</b>	<b>4.1</b>	<b>3.5%</b>	<b>-4.9%</b>
Gauze, bandages, plaster	4.4	5.7	2.4	4.0	3.4%	-3.4%
<b>Other</b>	<b>5.8</b>	<b>3.9</b>	<b>2.9</b>	<b>4.0</b>	<b>3.4%</b>	<b>-11.3%</b>
<b>Total</b>	<b>150.0</b>	<b>119.6</b>	<b>104.3</b>	<b>118.5</b>	<b>100.0%</b>	<b>-7.5%</b>

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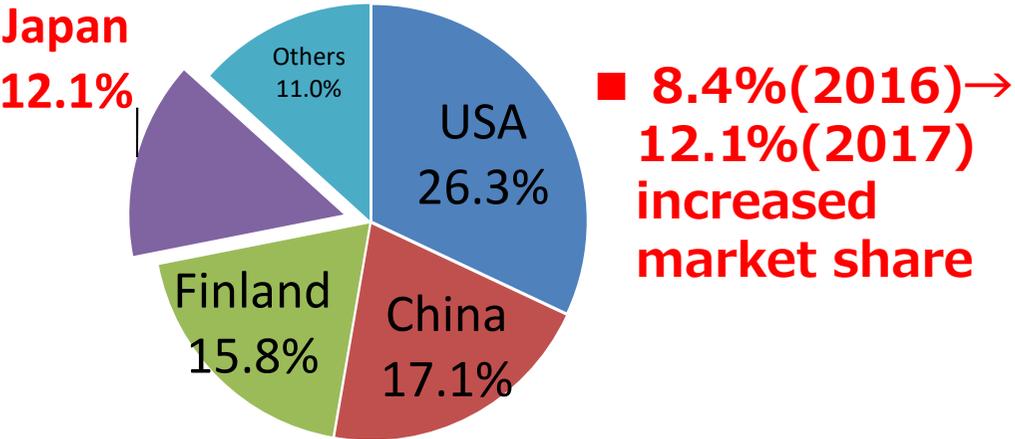
Source: Ministry of Industry, Foreign Trade and Services (SECEX, Aliceweb)

# Medical device Imports from Japan(2017)

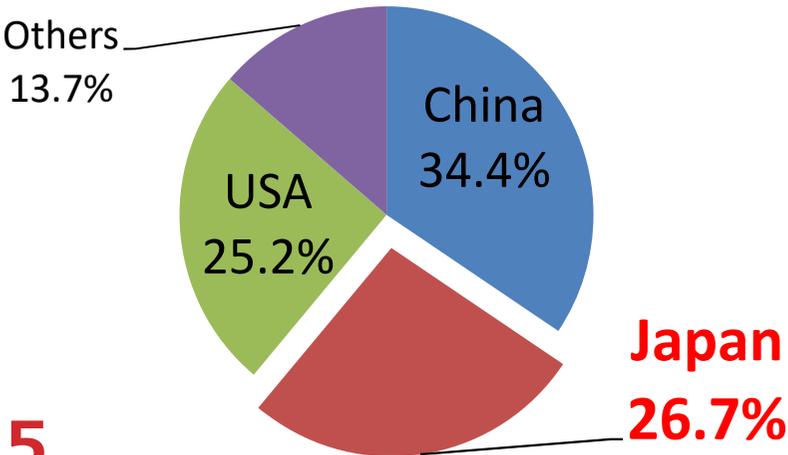
**Dental drill engines  
(HS Code : 901841)**



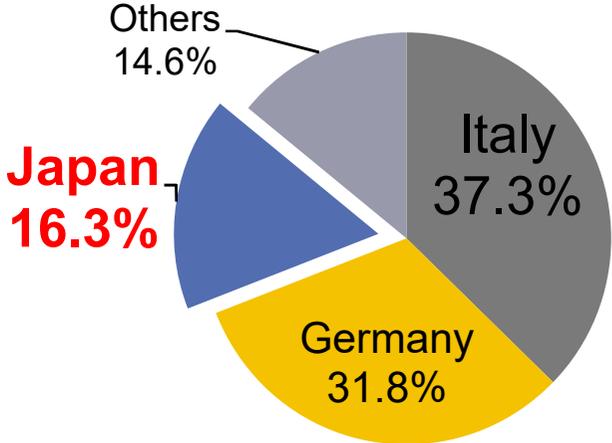
**Gauze, bandages, plaster and others  
(HS Code : 300510)**



**CT (HS Code : 902212)**



**Artificial tooth (HS Code : 902121)**



# Foreign Direct Investment by Country

(Units: US\$ FOB million)

	2016	2017		
	Value	Value	Share	Growth Rate
USA	6,544	11,078	18.4	69.3
Netherlands	10,540	10,894	18.1	3.4
British Virgin Islands	1,637	9,069	15.0	453.9
Luxembourg	7,395	4,305	7.1	△ 41.8
Germany	1,826	3,221	5.3	76.4
France	2,778	3,168	5.2	14.0
Spain	3,554	2,309	3.8	△ 35.0
Chile	846	1,620	2.7	91.5
Mexico	807	1,527	2.5	89.4
Italy	2,835	1,521	2.5	△ 46.3
Switzerland	965	1,288	2.1	33.4
UK	3,596	1,171	1.9	△ 67.4
Hong Kong	192	1,123	1.9	486.3
Bahamas Islands	125	1,122	1.9	794.7
Norway	2,186	939	1.6	△ 57.1
China	879	643	1.1	△ 26.8
<b>Japan</b>	<b>1,412</b>	<b>537</b>	<b>0.9</b>	<b>△ 62.0</b>
Others	5,636	4,809	8.0	△ 14.7
Total	53,754	60,345	100.0	12.3

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Note : Balance of payments basis, excluding reinvested earnings  
Source : Central Bank (BC)

# Japanese Medical device Companies in Brazil

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## **2010 and later~**

Growing interest to expand sales in Brazil  
Medium-sized companies starting to enter  
Brazilian market

### **Recently entered Brazilian market :**

**2010 FUJIFILM DO BRASIL**

**2012 NIHON KOHDEN DO BRASIL**

**2014 3-D Matrix MEDICAL TECHNOLOGY**

**2014 Paramount Bed do Brasil**

**2016 ASAHI INTECC CO. LTD.**

**2017 C-ENG**

**2017 SHOFU INC.**

# Japanese Medical device and Pharmaceutical Companies in Brazil

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## Expanding Investment !

### **Omron Healthcare Brasil**

2017 July, Production of household Electronic Blood Pressure Monitor

2018 May, Announcement of new factory in the city of Jundiai, State of Sao Paulo

### **Shimadzu do Brasil**

2016 May, Relocated head office to the city of Barueri, State of Sao Paulo

# Japanese Pharmaceutical Companies in Brazil

## Manaus Free Zone

- Farmaceutica do Hisamitsu Brasil



- Astellas Farma Brasil
- Eisai Laboratórios
- Otsuka Pharmaceutical
- Rohto do Brasil

## Sao Paulo

- Daiichi Sankyo Brasil
- Takeda Brasil

## Further market expansion

- 2014 Otsuka Pharmaceutical enters Health food sector through acquisition of Jasmine
- 2014 Sumitomo Dainippon Pharma and Daiichi Sankyo Brasil sign license agreement
- 2016 Rhoto do Brasil acquired 60% share of OPHTHALMOS S.A. and became a subsidiary

# Japan Brazil Joint Public-Private Sector Medical Seminar

**August 4, 2014** 1st Brazil-Japan Joint Public-Private Sector Open Seminar on Regulations in Pharmaceuticals and Medical Devices (Rosa Rosarum, São Paulo)



Remarks by Prime Minister Abe at the 1st Seminar

**September 10, 2015** 2<sup>nd</sup> Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices (JETRO Headquarters, Tokyo)

**October 4, 2016** 3<sup>rd</sup> Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices (Hotel Novotel Jaraguà, Sao Paulo)

**December 3, 2018** 4<sup>th</sup> Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices (JETRO Headquarters, Tokyo)



**2015** Presence of Dr. Barbosa, Director President of ANVISA in Japan  
Presentation of efforts in Brazil to expedite examination and to be more efficient. Expectation expressed towards ANVISA's initiative to reform. Confirmation was made for further bilateral cooperation.

**10** Remarks by Dr. Barbosa, Director President of ANVISA at the 2nd Seminar

# Improvement on Examination Process

## Actions by Brazil since 2014

2014 Nov.	1. Revocation of the validity (1year) of the Operating Permit, Autorização de Funcionamento de empresa (AFE) required for manufacturing and sales activities.
	2. Extension of renewal term of the GMP Certificate (from 2 to a maximum of 4 years).
2015 Jan.	3. The GMP audit services performed by ANVISA can now be performed by a third party agency (ANVISA certified agency).
	4. GMP audit information held by foreign authorities can now be used by ANVISA.
	5. Extension of product registration period (from 5 to maximum of 10 years).
2016 Aug.	6. Flexibility in transfer of product registration in transactions

## Results since 2015

- Shortened Registration Period for Class I, II, III, IV products
- Improved Transparency

**Outstanding Improvement!**

## Results since 2016

- ANVISA recognized 12 Audit Institutions, evaluated and approved through the MDSAP Program
- ANVISA's Resolution 212, January 22, 2018, expands period of validity of registered healthcare products from 5 to 10 years
- Process of acquiring Import License has been rationalized
- Customs clearance process has been accelerated

# Improvement on examination process

## For a Better Business Environment !

To provide latest medical technology to Brazilian healthcare industry and to Brazilian citizens !

■ We still see the progress of item 2. and 4. below with great interest

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■ Difficulties we are still facing,

For Example...

- Unharmonized period of validity between INMETRO's certification and ANVISA's registration (5 years vs 10 years)
- Limited term (only 2 years) of validity of type test reports and mandatory re-testing (stipulated in INMETRO's Ordinance 54, 2017)

# Improvement on examination process

## For a Better Business Environment !

Official meeting with ANVISA, INMETRO, and ABIMED  
Activities of Sub department of the Medical Equipment Sector of the  
Japan Chamber of Commerce

- December 8<sup>th</sup> 2017, ANVISA@ANVISA HQ in Brasilia
- April 12<sup>th</sup> 2018, INMETRO@INMETRO HQ in Rio de Janeiro,  
Rio Comprido
- September 3<sup>rd</sup> 2018, ANVISA@ANVISA HQ in Brasilia
- October 24<sup>th</sup> 2018, ABIMED@ABIMED HQ in Sao Paulo
- October 29<sup>th</sup> 2018, INMETRO@INMETRO laboratories in  
Rio de Janeiro, Xerem
- November 23<sup>rd</sup> 2018, INMETRO, ANVISA, ABIMED etc  
@INMETRO HQ in Rio de Janeiro,  
Rio Comprido

# Improvement on examination process

## For a Better Business Environment !

To provide latest medical technology to Brazilian healthcare industry and to Brazilian citizens !

For Example...

■ Unharmonized period of validity between INMETRO's Certification and ANVISA's registration (5 years vs 10 years)

⇒ **Align the period of validity between both authorities' regulation**

■ Limited period (only 2 years) of validity of type test reports and mandatory re-testing (stipulated in INMETRO's Ordinance 54, 2017)

⇒ **Abolish the term of validation in line with other countries' practices and exempt re-test if there is no model change**

# Activities of JETRO

## Information

- Information on the ANVISA approval and registration system and publication of reports related to medical device market in Brazil and other Latin American countries.
- Information on changes in the system through daily news letter “Tsusho Koho (Business News)”.

## Seminars

- Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices

## Supporting Efforts to Develop Business Environment

- Working together with Public-private sectors, participation in medical workshops

## Individual Consultation

- Support to Japanese companies in considering investment or to expand investment.
- Consultation on the medical device market and on new changes in the system in Brazil.
- Support to companies by experts.

## 【Study Reports】

### **November 2015 Latest Trend in Medical Device Market in L. America**

<https://www.jetro.go.jp/world/reports/2015/01/3c99cdea65145906.html>

### **March 2015 Overview of Approval and Registration System of ANVISA (Brazil’s National Health Agency)**

<https://www.jetro.go.jp/world/reports/2015/02/fcea1fc7565daddb.html>

### **October 2013 Medical Device Market in L. America**

<https://www.jetro.go.jp/world/reports/2013/07001514.html>

### **March 2012 Brazil’s Medical Device Market and Regulations**

<https://www.jetro.go.jp/world/reports/2012/07000870.html>

ブラジル国家衛生監督庁  
(ANVISA) の認証・登録制度の  
概要

2015年3月  
日本貿易振興機構（ジェトロ）  
サンパウロ事務所

# MUITO OBRIGADO !

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