



# Access to Regulatory Databases

Division of Registered Certification Body  
Assessment, PMDA

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1. Access to the list of foreign RMSs
2. Access to the information of recall

# 1. Access to the list of foreign RMSs

The screenshot shows the PMDA Web site interface. The browser address bar displays the URL: <https://www.pmda.go.jp/review-services/drug-reviews/foreign-mfr/0003.html>. The page title is "PMDA Web site". The main content area is titled "外国製造業者認定・登録番号の公表" (Public Disclosure of Foreign Manufacturer Registration Numbers). The page includes a navigation menu on the left with items like "審査関連業務" (Review-related business), "相談業務" (Consultation business), "治験関連業務" (Clinical trial-related business), "承認審査業務(申請・審査等)" (Approval/Review business (application, review, etc.)), "申請等手続き" (Application procedures), "審査等について" (About review, etc.), "承認情報" (Approval information), "原薬等登録原簿(MF)" (Active ingredients registration book (MF)), and "医薬品添加剤" (Pharmaceutical additives). The main content area contains text explaining the legal basis for the disclosure and provides two download links for the list of foreign RMSs: "認定・登録外国製造業者リスト(平成29年4月17日現在)" (Approved/Registered Foreign Manufacturer List (as of April 17, 2017)) in PDF format and "認定・登録外国製造業者リスト(平成29年4月17日現在)" (Approved/Registered Foreign Manufacturer List (as of April 17, 2017)) in zipped excel format. A note indicates that the files are in ZIP format and should be unzipped for use.

- ### How to verify
1. Access to PMDA web site.
  2. Download a list of foreign RMSs. (The list is provided by PDF format and zipped excel format.)
  3. Verify if the site is registered.

A list of foreign RMSs (PDF format)

A list of foreign RMSs (zipped excel format)

URL: <https://www.pmda.go.jp/review-services/drug-reviews/foreign-mfr/0003.html>

# Contents of the list of foreign RMSs

業者コード (法人部分)	業者 コード (事業 所部分)	認定・登録番 号	業態	認定区 分・登録	名称	所在地	認定・登録 (更新)年 月日	有効年月 日	廃止年月日	有効期限満 了に伴う更 新申請の提 出について	国名コード	国名
Code (Cooperatio n)	Code (Site)	Registration Number	Licens e Type	Registratio n Category	Name	Address	Date of Registratio n	Effective date	Abolition date	Submission of application for Registration Renewal	Country Code	Country Name
111314	005	BG30400709	医療機器 外国製造 業者	医療機器 登録	Abbott Va scular	26531 Yn ez Road, Temecula, CA, USA	2012/12/10	2017/12/ 9			304	アメリカ合衆 国

Note:

1) Registration Number is **10 digit number** consisting of numbers and alphabets.

Example of Registration number for a foreign RMS:

B G 3 0 4 0 0 7 0 9

**2 digit alphabet**

**8 digit numeral**

# 2. Access to recall information

## PMDA Web site

The screenshot shows the PMDA website's navigation menu with categories like Home, Review/Inspection, Safety Countermeasures, Health Protection, Regulatory Science, and International Activities. The breadcrumb trail is: Home > Safety Countermeasures > Information Provision > Medical Devices > Recall Information > Recall Information. The main content area is titled 'Recall Information (Medical Devices)' and includes a search function for recalls from 2015 onwards. A note states that recall information for Class I and II medical devices is emailed via PMDA Mediana. A list of recalls is provided for 2017, 2016, and 2015, with links to Class I, II, and III recalls.

このページをよくみるページ一覧に追加する 本文のみ印刷する

ホーム > 安全対策業務 > 情報提供業務 > 医療機器 > 注意喚起情報 > 回収情報

### 安全対策業務

- 安全対策業務の概要について
- 副作用・不具合等情報の収集・整理業務
- 安全対策の検討・実施に関する相談(企業向け)
- 患者・一般の方からの相談窓口
- 調査・分析業務
- 情報提供業務
  - 医薬品
  - 医療機器
  - 添付文書
- 注意喚起情報
  - 緊急安全性情報・安全性速報
  - 厚生労働省発表資料
- 回収情報
- 使用上の注意の改訂指示通知(医療機器)
- 医薬品・医療機器等安全性情報(厚生労働省発行)

### 回収情報(医療機器)

[回収情報検索\(2015年度以降\)](#)

2015年度以降の医薬品(体外診断用医薬品を含む)、医療機器、再生医療等製品、医薬部外品及び化粧品等の回収に関する情報が検索できます。

**回収一覧 医療機器**

医療機器のクラスI、クラスII回収情報は、PMDAメディアナビにより電子メールで配信しています。本情報のタイムリーな把握を希望される方は、[PMDAメディアナビ登録](#)をおすすめします。登録する方はこちらを [Click](#) してください。

#### 2017年度

- [クラスI](#)
- [クラスII](#)
- [クラスIII](#)

#### 2016年度

- [クラスI](#)
- [クラスII](#)
- [クラスIII](#)

#### 2015年度

- [クラスI](#)
- [クラスII](#)
- [クラスIII](#)

## How to verify

1. Prepare the below information.
  - Name of MAH
  - Date of the recall in Japan
2. Access to PMDA web site.
  - Use online translation service, when necessary.
  - Information is recalls which happened from April, 2015 is available.

URL: <http://www.pmda.go.jp/safety/info-services/devices/0054.html>

## Recovery information (medical equipment)


### [Retrieval information retrieval \(after FY 2015\)](#)

Information on the collection of pharmaceuticals (including in-vitro diagnostic drugs), medical devices, regenerative medicine products, quasi-drugs and cosmetics after FY 2015 can be searched.

### Collection list medical equipment

Class I and class II collection information on medical devices is delivered by PMDA Medinavi by e-mail.

If you wish to timely grasp this [information](#) , [PMDA Medinavi registration](#) is [recommended](#) .

To register please click here  please.

Our fiscal year starts in April and ends in March.

#### Fiscal Year 2017

- [Class I](#)
- [Class II](#)
- [Class III](#)

Recall information is categorized and uploaded on the web by the risk of the recall.

#### Fiscal Year 2016

- [Class I](#)
- [Class II](#)
- [Class III](#)

#### Fiscal Year 2015

- [Class I](#)
- [Class II](#)
- [Class III](#)

# Information of recall on the web

Fiscal year of the recall, risk classification

Screenshot of web page translated by online web service

## Fiscal 2010 Class III (Medical Equipment)

number	Posting date	type	common name	Sales name	Manufacturer and distributor name	Remarks
3-2401	2017/05/31	Medical equipment	Stationary diagnostic X-ray generator	<a href="#">Diagnostic X-ray high voltage device UD 150 B - 40 SPT</a>	Shimadzu Corporation	
3-2400	2017/05/29	Medical equipment	General purpose image diagnostic equipment workstation program	<a href="#">Zeocube</a>	Ziosoft Corporation	2017/6/7 "2. Target Lot, Quantity and Shipment Timing" Correction
3-2399	2017/05/26	Medical equipment	Aortic cannula	<a href="#">Cannula flexure mate for extracorporeal circulation (Adapter kit ADKN-04 for infusion of mvocardial protective liquid)</a>	Izumi Kogyo Kogyo Co., Ltd.	
3-2397	2017/05/22	Medical equipment	Refractor	(1) <a href="#">Accessories for "Comp Vision CV - 5000" Miracle chart MC - 4S</a> (2) <a href="#">Accessory of "Comp Vision CV - 5000" Panel chart PC - 50S</a> (3) <a href="#">Accessory of "Comp Vision CV - 5000" Panel chart PC - 50SB</a>	Topcon Corporation	2017/5/24 Correction of "9. Contact person and contact information"
3-2396	2017/05/15	Medical equipment	Orthopedic bone cement	<a href="#">Surgical simplex</a>	Japan Striker Co., Ltd.	
3-2395	2017/05/08	Medical equipment	Plastic cannula type sterilized puncture needle	<a href="#">Protective I. V. catheter</a>	Smith Medical Japan Co., Ltd.	2017/5/10 Correction of "4. Reason for collection"
3-2394	2017/04/21	Medical equipment	Reducer	<a href="#">Da Vinci Series Cannula Seal</a>	Intuitive Surgical Limited Liability Company	
3-2391	2017/04/13	Medical equipment	Dental material warmer	(1) <a href="#">Cute cartridges</a> (2) <a href="#">Cute syringe</a>	Morita Tokyo Manufacturing Co., Ltd.	
3-2390	2017/04/07	Medical equipment	Respiratory function measuring device	<a href="#">Resp Trace</a>	Sanita Shoji Co., Ltd.	Correction of "9. Person in charge and contact information" 2017/4/11

Generic Name of the device

Name of MAH

Sales name of the device in Japan

# Thank you!

**Division of Registered Certification Body Assessment,  
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