HIGH PRESSURE SYRINGE

P/N: 400107

Compatible with Medtron Accutron CT-D Injector

Contents: 1-200ml Syringe
1-Quick Fill Tube

Packing: 50PCS/CASE

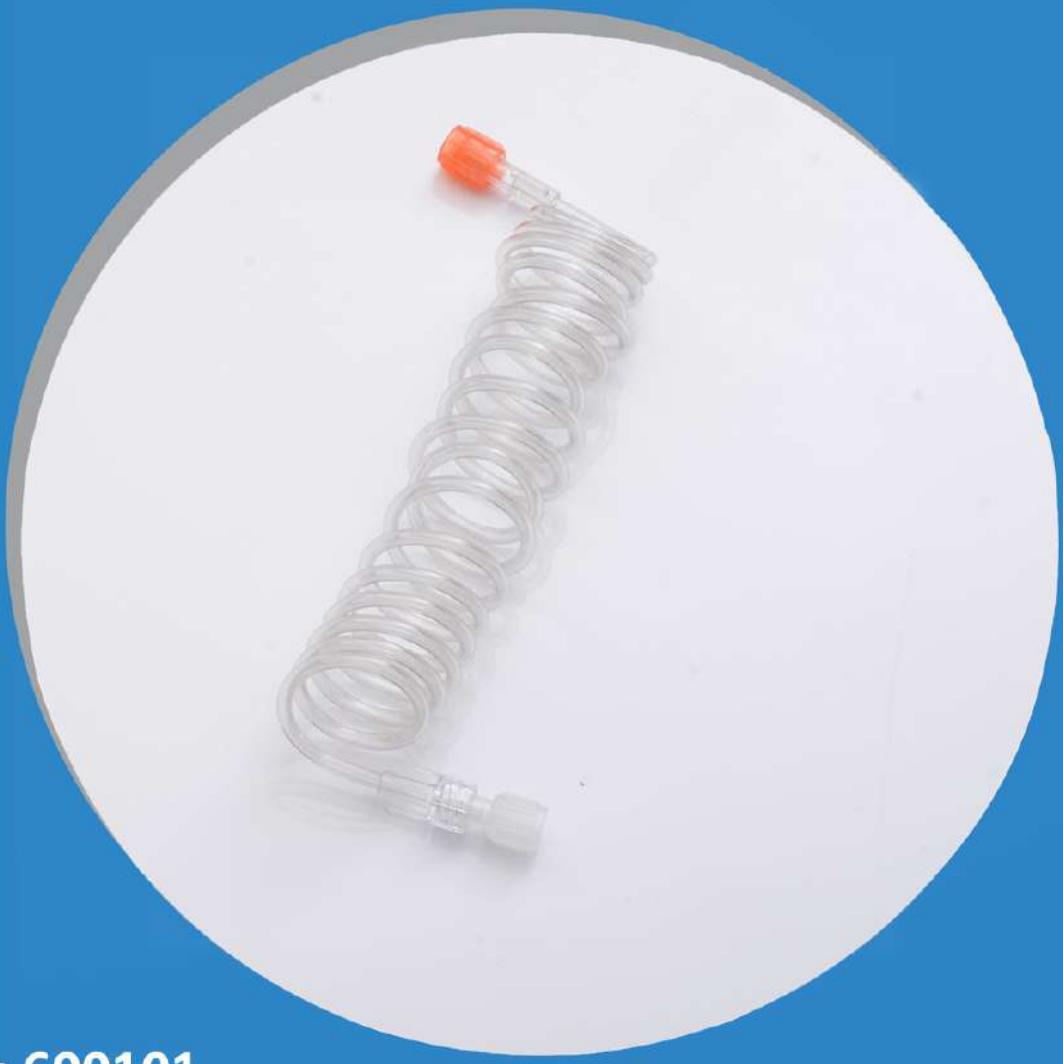
Digitally signed by Volcovschi Mihai
Date: 2026.03.09 10:46:00 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

FDA 510(K)

CE 0123

antmed
Partner For Life

Pressure Connecting Tube



P/N: 600101

Length: 150cm

Pressure: 350PSI

Description: 150cm CT Coiled Tube

Used for CT single head injection system

Packing: 200PCS/CASE

FDA 510(K)

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Pressure Connecting Tube

P/N: 680301

Length: 250cm

Pressure: 350PSI

Description: 250cm MRI Coiled Y Tube with single check valve

Used for MR injection system

Packing: 200PCS/CASE

FDA 510(K)

CE 0123

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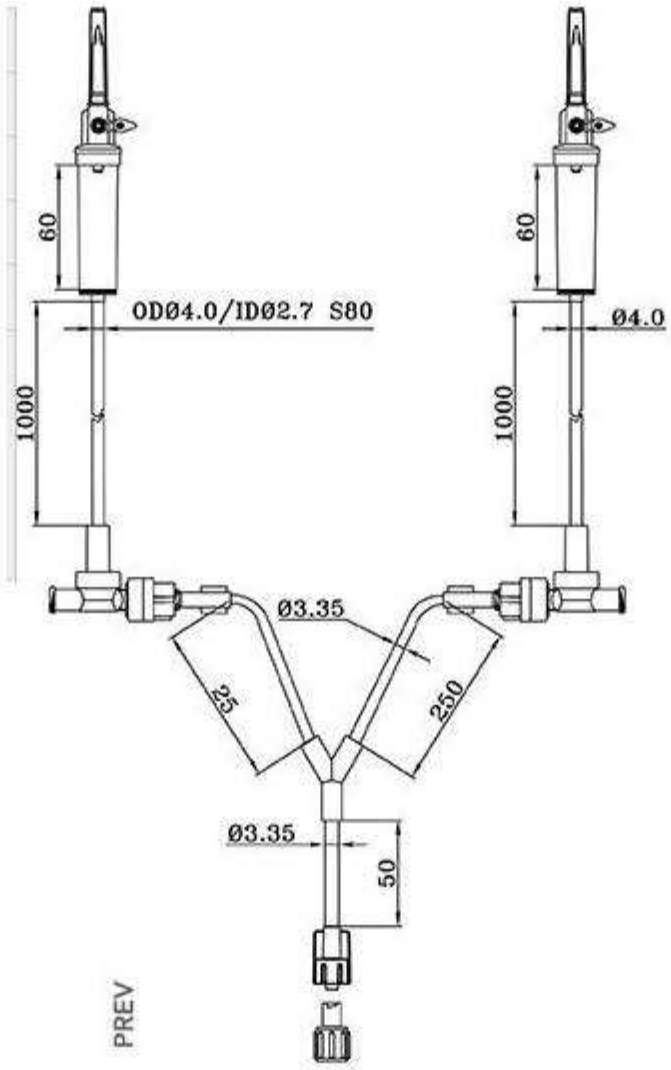
Partner For Life

Pressure Connecting Tube



P/N 800101

Length: 100/100cm

Pressure: 350PSI

Description: CT Dual Head System with double drip chamber

Use for CT Dual Head Injector System

antmed
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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 004593 0011 Rev. 00

Manufacturer:

Shenzhen Antmed Co., Ltd.
18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000029659

Authorized Representative:

MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 004593 0011 Rev. 00

Report No.: BJ23081103

Valid from: 2024-02-06
Valid until: 2029-02-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 004593 0011 Rev. 00

Classification:	Class IIa
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A030201 - EXTENSIONS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	-
Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The product is used for monitoring the arterial pressure and central venous pressure of patients, and in conjunction with a patient monitor with invasive blood pressure monitoring function.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-06	BJ23081103	Initial issuance

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

G11 004593 0012 Rev. 00

Manufacturer:

Shenzhen Antmed Co., Ltd.
18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000029659

Authorized Representative:

MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 004593 0012 Rev. 00 0012 Rev. 00

Report No.: BJ23081103

Valid from: 2024-02-06
Valid until: 2029-02-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

G11 004593 0012 Rev. 00

Classification:	Class I
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function

Classification:	Class I
Device Group:	A030201 - EXTENSIONS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	C010401 - CARDIAC ANGIOGRAPHY DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function

Classification:	Class I
Device Group:	C900101 - HAEMOSTASIS VALVES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following:	-None-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-06	BJ23081103	Initial issuance

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 004593 0004 Rev. 07

Holder of Certificate: **Shenzhen Antmed Co., Ltd.**
18 Jinhui Ave., Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales and Distribution of High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 004593 0004 Rev. 07

Report No.: BJ24081103

Valid from: 2024-10-08
Valid until: 2026-10-30

Date, 2024-10-08

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 004593 0004 Rev. 07

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Shenzhen Antmed Co., Ltd.
18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

The Provision of Management Services for High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.

Shenzhen Antmed Co., Ltd.
No.3 Hualian Ave, Songshanhu District, 523800 Dongguan, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Sales and Distribution of High Pressure Syringe, Control Syringe, Color Syringe, Bladder Catheter Valve, Manifold, Pressure Connecting Tube, Hemostasis Valve, Introducer Set, Inflation Device, Positive Needlefree Connector, Disposable Pressure Transducer, Disposable Pressure Transducer Kit, Manifold Kit, PTCA Kit, Injection Tubing System, I.V Catheter for Single Use, Filling Device, Adaptor for High Pressure Syringe, Multi-Patient Syringe System, Contrast Media Injectors, Transfer Set.

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DECLARATION OF CONFORMITY

Doc ID: ANT/CE-HPS-07

MANUFACTURER:	**SHENZHEN ANTMED CO.,LTD.** 18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, CHINA
SRN OF THE MANUFACTURER:	**CN-MF-000029659**
MEDICAL DEVICE:	**High Pressure Syringe**
MODEL:	CM-60, CM-60/60, CM-65, CM-65/65, CM-100, CM-100/100, CM-65/115, CM-125, CM-130, CM-140, CM-150, CM-190, CM-200, CM-130/200, CM-100/200, CM-60/100, CM-60/200, CM-190/190, CM-200/200
BASIC UDI-DI:	**69457644HPS0000001HG**
CLASSIFICATION - ANNEX IX:	Class IIa, Rule 2
CONFORMITY ASSESSMENT ROUTE:	Annex IX of MDR on (EU) 2017/745

WE, THE MANUFACTURER, HERE WITH DECLARE ON OUR OWN RESPONSIBILITY THAT THE MEDICAL DEVICE: MEET ALL THE PROVISIONS OF THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICE, WHICH APPLY TO IT. EVERY ARTICLE WE SELL IS COVERED BY A TECHNICAL DOCUMENTATION. TECHNICAL DOCUMENTATION ARE PROVIDED TO THE EUROPEAN AUTHORIZED REPRESENTATIVE AND KEPT UP TO DATE BY US.

NOTIFIED BODY:	***TÜV SÜD PRODUCT SERVICE GMBH*** ***RIDLERSTRAßE 65, 80339 MUNICH, GERMANY***
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	***G10 004593 0011 REV. 00***
EXP. DATE:	***2029-02-05***
EC REP ***EC-REP:***	***MedNet EC-Rep C IIb GmbH*** ***Borkstrasse 10, 48163 Muenster, Germany***
SRN OF THE EC-REP:	***DE-AR-000011194***

START OF CE-MARKING: ***2024-02-06***

PLACE, DATE OF DECLARATION:	**Shenzhen, 2024-02**
LEGALLY BINDING SIGNATURE:	**NAME: FENG GAO** **POSITION: PERSON RESPONSIBLE FOR REGULATORY CONFORMITY (PRRC)**

DECLARATION OF CONFORMITY

Annex specification:
P/N:100101; P/N:100102; P/N:100103; P/N:100104; P/N:100104A; P/N:1001048; P/N:100106; P/N:100110; P/N:100111; P/N:100201; P/N:100202; P/N:100205; P/N:100301; P/N:100302; P/N:200101; P/N:200104B; P/N:200105A; P/N:200105B; P/N:200107; P/N:200201; P/N:200204; P/N:200301; P/N:300101; P/N:300102; P/N:300105; P/N:300105A; P/N:300105B; P/N:300106; P/N:300201; P/N:300202; P/N:300301; P/N:400101; P/N:400102; P/N:400103; P/N:400104; P/N:400105; P/N:400106; P/N:400301A; P/N:4003018; P/N:400203; P/N:400302; P/N:400303; P/N:400305; P/N:400306; P/N:400307; P/N:400308; P/N:400110; P/N:400111; P/N: 500101; P/N: 500102; P/N:100204; P/N: 100107

Declaration of Conformity

Doc ID: ANT/CE-PCT-07

Manufacturer:	SHENZHEN ANTMED CO.,LTD. 18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, CHINA
SRN of the manufacturer:	CN-MF-000029659
Medical Device:	Pressure Connecting Tube
Model:	5cm, 10cm, 15cm, 20cm, 25cm, 30cm, 40cm, 50cm, 60cm, 75cm, 80cm, 90cm, 100cm, 110cm, 120cm, 130cm, 150cm, 180cm, 200cm, 250cm, 300cm
REF	Please see annex I.
Basic UDI-DI:	69457644PCT0000002G2
Classification - Annex IX:	Class Is, Rule 2
Conformity assessment Route:	Annex IX of MDR on (EU) 2017/745

We, the manufacturer, here with declare on our own responsibility that the medical device:
meet all the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical device, which apply to it. Every article we sell is covered by a technical documentation. Technical documentation are provided to the European Authorized Representative and kept up to date by us. We, the manufacturer, is exclusively responsible for the declaration of conformity.

Applied Standard	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 80369-7:2021, EN ISO 10993-1:2020, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-7:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021,EN ISO 10993-17:2023, EN ISO 10993-18:2020/A1:2023, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11134:2014/A1:2019, EN 62366-1:2015/A1:2020, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023, ASTM F 1980-21, ASTM D 4169-23e1, EN ISO 15223-1: 2021.
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany
Identification Number:	CE 0123
(EC) Certificate(s):	G11 004593 0012 Rev. 00
Exp. Date:	2029-02-05
EU REP:	MedNet EC-Rep C IIb GmbH Borkstrasse 10, 48163 Muenster, Germany
SRN of the EC-REP:	DE-AR-000011194

Start of CE-marking: 2024-02-06

Place, Date of Declaration:	Shenzhen, 2025-10-29
Legally binding Signature:	Xia Gu Name: XIA GU POSITION: Person Responsible for Regulatory Conformity (PRRC)

Declaration of Conformity

Annex I REF List

SN	REF	SN	REF	SN	REF	SN	REF
1	600101	39	650106	77	800102	115	HBR025
2	600102	40	650107	78	800103	116	HBR030
3	600103	41	650108	79	800104	117	HBR040
4	600104	42	650109	80	800105	118	HBR050
5	600105	43	650110	81	800106	119	HBR060
6	600106	44	650111	82	800107	120	HBR075
7	600107	45	650112	83	800108	121	HBR080
8	600108	46	650115	84	PTMF02	122	HBR090
9	600109	47	650116	85	PTMF03	123	HBR100
10	600112	48	650117	86	PTMF04	124	HBR120
11	600113	49	650118	87	PTMF06	125	HBR130
12	600122	50	650119	88	PTMF08	126	HBR150
13	600133	51	680301	89	PTMF09	127	HBR180
14	600134	52	680302	90	PTMF10	128	HBR200
15	600135	53	680303	91	PTMF11	129	HBR250
16	600137	54	680304	92	PTMF12	130	HBU150
17	600150	55	680305	93	PTMF13	131	HBU200
18	600151	56	680306	94	PTMF14		
19	600155	57	700201	95	PTMF16		
20	600158	58	700202	96	PTMF17		
21	601150	59	700203	97	PTMF18		
22	601155	60	700204	98	PTMF19		
23	602101	61	700205	99	PTMF51		
24	602151	62	700206	100	PTMF59		
25	602251	63	700208	101	PTMF60		
26	611005	64	700207	102	PTMF61		
27	611007	65	700209	103	PTMF62		
28	611009	66	700211	104	PTMM05		
29	611015	67	700212	105	PTMM06		
30	612801	68	700213	106	PTMM08		
31	612825	69	700214	107	PTMM12		
32	630050	70	700215	108	PTMM16		
33	640001	71	700216	109	PTMM19		
34	640002	72	700217	110	PTMM59		
35	640005	73	700218	111	HBR005		
36	650101	74	700219	112	HBR010		
37	650102	75	700220	113	HBR015		
38	650105	76	800101	114	HBR020		