



MA-UDI

Unique Identification of Medical Device

Coding Manual

for China

China National Version 2.1

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ZIIOT RESEARCH INSTITUTE

Zhongguancun Industry and Information Research Institute of Two-Dimensional Code
Technology

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Foreword

Unique Device Identification (UDI) refers to unique marking of medical devices and in-vitro-diagnostics, as well as to registration of specific product data in national UDI registries. Under the umbrella of the International Medical Device Regulators Forum (IMDRF), countries and regions establish rules for implementing UDI in accordance with national laws. While some features may be the same, there are also specific requirements that vary from country to country. For example, countries and regions accredit certain coding systems and the organizations responsible for them. The coding rules specified in this manual are accredited for UDI in China. The supporting organization is the ZIIOT (Zhongguancun Industry and Information Research Institute of Two-dimensional Code Technology), which provides documentation and services. In addition to assigning unique company IDs and UDIs, ZIIOT provides a UDI platform for additional functions such as tracking and tracing the products.

This manual focuses on the specifications for UDI codes flagged with the issuing agency code “MA,” known as the “MA code.” For China-UDI, the ISO/IEC 15459 issuing entity code “MA” is used without an additional system identifier, and the Production Identifier (PI) data elements are prefixed with specific identifiers defined by ZIIOT, called MA Data Identifiers. The manual specifies the data structure for encoding UDI data elements on the preferred data carrier, the “ISO/IEC 18004 QR Code,” including the unique product identifier and the production identifier with product parameters such as lot/batch, serial number, date of manufacture, and expiration date of the product.

Prepared by ZIIOT on behalf of the joint editors Zhang Chao, Du Zhihui, Niu Xiaobing, Liu David, He Lihui, and Heinrich Oehlmann (EDCi).

Version	Date	Key message	Proposers
V2.1	August 3, 2026	Illustration MA UDI format and MA data identifiers for UDI China application	Xiaobing NIU, David LIU, Heinrich Oehlmann

Part I Introduction of UDI

Chapter 1 Introduction

Unique Device Identification (UDI) serves as the electronic identity of medical devices. A Unique Device Identification data carrier is a medium for storing and transmitting the Unique Device Identification of medical devices, and a Unique Device Identification database is a database that stores the device identifiers of Unique Device Identifications and their associated information. These three components collectively constitute the Unique Device Identification system for medical devices.

Announcement No. 66 of 2019 issued by the National Medical Products Administration (NMPA) stipulates the governing rules for the medical device Unique Device Identification system. All medical devices distributed and utilized within the territory of China shall comply with such rules with regard to their UDI systems.

The establishment of the UDI system facilitates the rapid and accurate identification of medical devices throughout the production, distribution and clinical utilization links via information-based approaches; enables the sharing and integration of product regulatory data; fosters innovative supervision models and improves supervision efficiency; and strengthens full-lifecycle management of medical devices, integrates governmental supervision with social governance to build a collaborative co-governance framework, and further elevates the level of safeguards for the safe and effective use of medical devices.

Part II Coding rules for MA unique device identification (MA-UDI)

Chapter 2 MA-UDI code structure and MA data identifiers

2.1 MA-UDI code structure

MA-UDI code is divided into three segments, and there are different data elements in each segment, as shown in Figure 2-1:

- 1) UDI Device Identifier (UDI-DI) with IAC, CIN and product reference;
- 2) UDI Production Identifier (UDI-PI) with variable data (e.g., expiration date, production date, lot/batch number, SN) ;
- 3) Optional manufacturer information (add-on), e.g., second check digit.

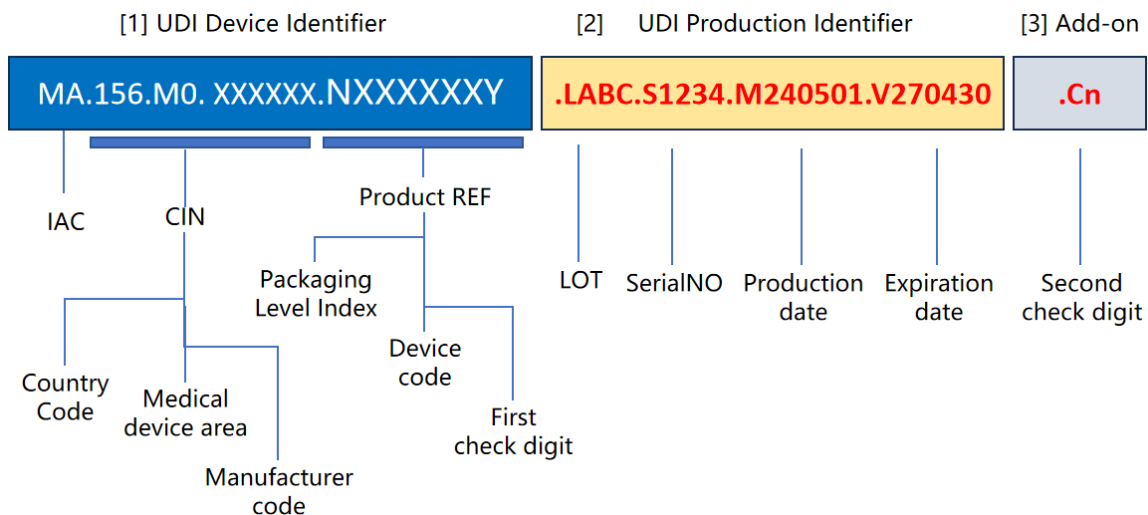


Figure 2-1 MA-UDI coding structure

The first segment UDI-DI includes Issuing Agency Code (IAC), Company Identification Number (CIN) and Product REF.

The IAC “MA” for ZIIOT is assigned by the Registration Authority AIM Glob according to ISO/IEC 15459-2.

The CIN is a construct containing an ISO 3166-1 country code, a medical-device area code, and manufacturer code and separator “.”.

The data elements are separated by the “Dot” (.). It shows as follows:

<IAC> <.> < country code> <.> < medical-device area code> <.> <manufacturer code> <.>

The product REF is the product number for a specific medical device.

The following example shows the structure of UDI-DI,

<MA.276.M0.100001.> <*Product REF> <**Y>

**Note: Product REF includes the leading 1-digit PLI (see 3.2.1).*

***Note: "Y" stands for the check digit.*

The second segment is UDI-PI. There are several MA data identifiers defined for this segment (see clause 2.2.3).

The MA-UDI code will be embedded in the MA coding structure using MA data identifiers and encoded in a symbol like a QR code or Data Matrix in the sequence:

<UDI-DI> <.> <UDI-PI> <.> <add-ons>

2.2 MA data identifiers and data elements

According to the management requirements of UDI of NMPA, MA-UDI uses the following MA data identifiers and data elements. Data elements with * are required for code generation as mandatory data elements.

Table 2-1 MA data identifiers and data elements for MA-UDI

MA data identifier	Data element name	Data format	Example
UDI Device Identifier (UDI-DI) *			
	CIN*	IAC+.n3.an2.n6	MA.276.M0. 100001
	Product REF*	.n1an1...18n1	.0MEDIX1295, see 3.2.1
UDI Production Identifier (UDI-PI)			
.M	Production date	YYMMDD	260204
.V	Expiration date, the last day of validity	YYMMDD	300203
.E	Expiration date, the first day of expiration	YYMMDD	300204
.L	Lot/Batch number	an...20	20260601
.S	Serial number	an...20	1234
Add-on data			
.D	Sterilization batch number	an...20	B260601
.Y	China healthcare security code	an...27	C010101001030010153012 34567
.C	Check digit at the end of MA-UDI code	n1	0~9

2.2.1 UDI Device identifier (UDI-DI) *

The data element of UDI device identifier (UDI-DI) is coded by the IAC code "MA", the separator ".", Company Identification Number (CIN), separator ".", and product REF. The composed data element shall appear as the first data field. UDI-DI is required.

Among them, the CIN includes the 3-digit country code (ISO 3166-1), separator ".", 2-character industry code "M0" (Assigned by ZIIOT and dedicated to UDI application in China), separator ".", and 6-digit manufacturer code.

The product REF consists of the 1-digit Packaging Level Index (PLI) (0~9), the alphanumeric device code of 1~18 characters, and is terminated by the 1-check digit.

The PLI is placed in front of the product REF. Level 0~9 are defined as,

- PLI 0: for the Unit of Use (UoU), specifically for direct part marking to differentiate from a higher-level package
- PLI 1: for a one-piece package,
- PLI 2 to 9: for the higher-level multiple-piece packages, like 2 for a 10-pack, 3 for a 50-pack, etc

The manufacturer can set the PLI according to the packaging scheme.

The PLI belongs to the UDI-DI; see example with PLI "N" in Figure 2-1.

2.2.2 First check digit

In order to ensure the reliability of coding and decoding of the UDI-DI, 1 check digit is provided, which is located at the end of the UDI-DI. "Y" represents a check digit in the following example, and the exact value will be calculated by the UDI check digit algorithm "LUHN".

An example of the position of the check digit in the code structure is shown as:

MA.276.M0.100001.0MEDIX129Y.M260204.V290203.L1234.S51239475

The second check digit is introduced in clause 2.2.4.

2.2.3 UDI Production identifier (UDI-PI)

The UDI Production identifier (UDI-PI) is composed of data elements of production date, expiration date, batch number, serial number, etc.

Each data element of the UDI-PI is headed by a MA data identifier and separated from each other by ".".

1) Production date

The data element of production date consists of the MA data identifier ".M" and the data of production date of the medical device. The field of production date is a 6-digit fixed-length number, and the format is YYMMDD, which is composed of year (the last two digits of the year), month (2 digits) and day (2 digits) in order.

2) Expiration date, the last day of validity

The data element of the last day of validity consists of the MA data identifier ".V" and the expiration date of the medical device. The medical device is still valid until the end of this day.

The field of expiration date is a 6-digit fixed-length number, which is composed of year (the last two digits of the year), month (2 digits) and day (2 digits) in order.

3) Expiration date, the first day of expiration

The data element of the first day of expiration consists of the MA data identifier ".E" and the date of the first day. The medical device starts invalid at the beginning of this day. The field of this date is a 6-digit fixed-length number, which is composed of year (the last two digits of the year), month (2 digits) and day (2 digits) in order

4) Lot/Batch number

The data element of batch number consists of the MA data identifier ".L" and the data of the batch number of the medical device. The field of batch number is alphanumeric characters with variable length and contains all characters in Table 2-2. The maximum length of this field is 20.

5) Serial number

The data element of serial number consists of the MA data identifier ".S" and the data of the serial number of the medical device item. The field of serial number is alphanumeric characters with variable length and contains all characters in Table 2-2. The maximum length of this field is 20.

2.2.4 Add-on data

After UDI-PI data elements, the manufacturer may add additional data elements applied with the separator "." and MA data identifiers in a continuing sequence. Generally, put it after PI and keep it as short as possible.

1) China Healthcare security code

It is useful to include a China healthcare security code assigned by the China National Healthcare Security Administration (NHSA) to the medical device. The data element of the China health security code is optional. It consists of the MA data identifier ".Y" and the string assigned by NHSA.

2) Second check digit

The data element of the second check digit is optional. It consists of the MA data identifier ".C" and the check digit. The second check digit is placed at the end of the whole UDI code. The second check digit is calculated over all of the data characters starting from the first data element in the UDI-PI to the last data element except the second check digit itself. The check-digit algorithm for the second check digit is the same as for the first check digit.

Example: <UDI-PI><.Yxx><.Cn> n is the second check digit

2.3 MA-UDI code character set

The MA-UDI coded character set complies with ISO/IEC 646 standard, and the supported combinations of Arabic numerals and English letters are shown in Table 2-2 below.

Table 2-2 MA-UDI code character set

!	"	'	(	)	*
+	,	-	>	<	=
:	0	1	2	3	4
5	6	7	8	9	A
B	C	D	E	F	G
H	I	J	K	L	M
N	O	P	Q	R	S
T	U	V	W	X	Y
Z	_	a	b	c	d
e	f	g	h	i	j
k	l	m	n	o	p
q	r	s	t	u	v
w	x	y	z		

It is strongly suggested to use only capital letters (A~Z) and numbers (0~9) in product REF, LOT and Serial number data elements.

Chapter 3 MA-UDI check digit calculation

3.1 MA-UDI check digit calculation algorithm

The algorithm of MA-UDI check digit calculation is designed based on the “Luhn algorithm”.

The first check digit is at the end of the UDI-DI, that is, as the last digit of the Product REF data element.

The input for the first check digit calculation includes the first segment. After calculation, the result check digit will be appended to the end of the first segment. For example, in the following UDI-DI (without a check digit), the input is “MA.276.M0.100001.0MEDIX129”, and the calculated check digit is “5”, so the UDI-DI is “MA.276.M0.100001.0MEDIX1295”.

The second check digit is at the end of the whole UDI code.

3.2 Check digit calculation procedure

The MA-UDI check digit calculation is divided into five steps, as follows:

Step 1: Convert all input characters of the calculation algorithm into corresponding numbers. The following is the corresponding table of characters and numbers. Letters are case sensitive.

Table 3-1 Numerical value assignments

for computing the MA-UDI data format Check Character

0=0	1=1	2=2	3=3	4=4	5=5	6=6	7=7
8=8	9=9						
A=10	B=11	C=12	D=13	E=14	F=15	G=16	H=17
I=18	J=19	K=20	L=21	M=22	N=23	O=24	P=25
Q=26	R=27	S=28	T=29	U=30	V=31	W=32	X=33
Y=34	Z=35						
a=36	b=37	c=38	D=39	e=40	f=41	g=42	h=45
i=46	j=47	k=48	l=49	m=50	n=51	o=52	p=53
q=54	r=55	s=56	t=57	u=58	v=59	w=60	x=61
y=62	z=63						
-=64	. =65	@=66	\$=67	, =68	*=69	+=70	%=71
/=72	#=73	!=74	^=75	~=76			

Computing example:

MA.276.M0.100001.0MEDIX129

The conversion numbers of object identifiers in the above coding examples are as follows:

- (1) The UDI-DI segment is converted into a serial number according to the assignment in Table 3-1. An example is shown in Figure 3-1 as follows:

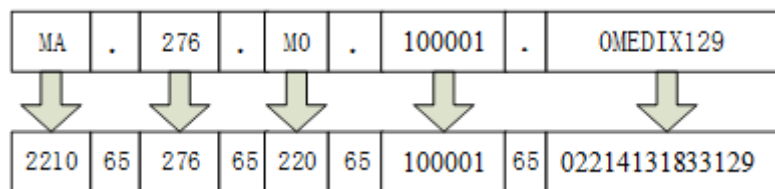


Figure 3-1 Convert the input into numbers

The converted string is as follows:

22106527665220651000016502214131833129

Step 2: After the first step, the UDI-DI is converted into serial numbers, and all the numbers are connected as a new numeric string. The string number is in the order from right to left. Multiply the even-digit number by 2 to get N. If N is larger than 9 (e.g., $N = 8 \times 2 = 16$), then calculate N by summing up the units digit and tens digit of N (e.g., $N = 16$, then calculate $1 + 6 = 7$ to update the

N); If N is less than 9, no calculation is required. Finally, replace the even digit with N.

e.g., 22106527665220651000016502214131833129 red numbers are even digits from the right to the left.

The first even digit is 2, $N = 2 * 2 = 4$. Because N is less than 9, replace 2 with 4. The result is:

22106527665220651000016502214131833149

The second even digit is 3, $N = 2 * 3 = 6$. Because N is less than 9, replace 3 with 6. The results are as follows:

22106527665220651000016502214131836149

Other even digits are processed in the same way. The final results are as follows:

42203547361240352000013502418161736149

Step 3: Sum up each number in the result numeric string after Step 2.

All the numbers in the result number string 42203547361240352000013502418161736149 are summed, and the sum is 115.

Step 4: Perform the "modulo 10" operation on the added result value 115 after the operation in Step 3 in order to make the modulo 10 operation result value equals 0.

Specific formula: (sum of other digits except check digit Y + Y) mod 10 = 0

$(115 + Y) \bmod 10 = 0$, and the calculated value of Y is 5.

Step 5: Complete the UDI-DI with the calculated check digit as follows:

MA.276.M0.100001.0MEDIX1295

Figure 3-2 Example of UDI-DI with calculated Check digit calculation "5"

3.3 Second check digit

The second check digit is at the end of the whole code, beginning with the MA data identifier ".C".

All the second segment (UDI-PI) and the third segment (without ".Cn") are input into the check digit algorithm, and the output is the second check digit.

For example, the input UDI without check digits is

54PMA.276.M0.100001.0MEDIX129.M260204.V290203, and after calculation, it will generate the first check digit 5 and the second check digit 7. So the registered UDI will be 54PMA.276.M0.100001.0MEDIX1295.M260204.V290203.C7.

Chapter 4 Unique identification label and data carrier of MA-UDI

4.1 MA-UDI barcode symbols, human-readable interpretation (HRI), human translation, short titles and pictograms

4.1.1 MA-UDI barcode symbols

For UDI the common ISO/IEC standards for linear and 2D-barcode symbols are appropriate.

The suitable symbologies for carrying UDI codes are ISO/IEC 15417 Code 128, ISO/IEC 16022 Data Matrix with ISO/IEC 21471 DMRE (Data Matrix Rectangular Extension) and ISO/IEC 18004 QR Code. The most recommended symbology for China is the QR Code.

Note: While Data Matrix and DMRE feature automatic error correction, the error correction level for QR codes must be specified when generating the QR code symbol; for general UDI applications, level “M” with 15% error correction is recommended (L 7%, M 15%, Q 25%, H 30%).

4.1.2 Quality Grade for barcode symbols

Quality Grade for symbols shall be "C" as a minimum according to ISO/IEC 15415 for 2D-barcode symbols and according to ISO/IEC 15416 for Code 128.

Note: 2D-barcode symbols directly marked on items (DPM) and/or symbols printed with round or non-connected dots should specify quality measurement using the quality extension ISO/IEC 29158 to ISO/IEC 15415, and for reading adequate DPM scanners might be required.

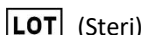
4.1.3 MA-UDI human readables represent the encoded data

There are different human readables for showing the content of the barcode in a human readable format:

- a) Human-readable Interpretation (HRI) representing the encoded data in machine readable form of the code in MA code data structure, placed adjacent to the barcode symbol; the HRI is mandatory;
- b) Human translation of the single encoded data elements in Chinese language proceeding the UDI data elements as single fields, the Chinese text is recommended;
- c) Short titles in English language for human information proceeding the UDI data elements as single field, the short titles are optional;
- d) Pictograms for human information proceeding the UDI data element single fields, pictograms are optional.

The relationship between MA data elements and human readable translation in Chinese, English short titles and pictograms is shown in Table 4-1. The data elements of the product identifier (PI) of the UDI code are optional.

Table 4-1 MA data identifiers and corresponding human translation, short titles and pictograms

MAdata identifier (encoded and in HRI)	Description	Human translation in Chinese	Short titles in English	Pictogram
MA...	Product REF	产品编码	REF	
.M	Production date (PI)	生产日期	MFD	
.V	Expiration date, the last day of validity (PI)	有效期至	EXP	 Last day of validity
.E	Expiration date, the first day of expiration (PI)	失效日期	EXP	 First day of expiration
.L	Lot/Batch number (PI)	生产批号	LOT	
.D	Sterilization batch number (PI)	灭菌批号	Steri-Batch	
.S	Serial number (PI)	序列号	SN	
.Y	China healthcare security code (PI)	医保编码	CHS	Not applicable
Not in bar code	Unique device identification conformity indication	医疗器械唯一标识	UDI	

Pictograms of table 4-1 are according to the Chinese standard YY/T 0466.1 (ISO 15223-1:2021).

4.1.4 Label examples

As data carriers for MA-UDI codes linear barcodes (Code 128) or two dimensional symbols can be used like ISO/IEC 18004 QR code, ISO/IEC 16022 Data Matrix or ISO/IEC 21471 DMRE.

If Code 128 is used, the MA-UDI string might be split into two symbols, one symbol for the UDI-DI and a second symbol with UDI-PI (not illustrated).

Figure 4-1, 4-2 and 4-3 are showing MA-UDI labels applied with QR code. It contains UDI-DI and PI information in the QR Code applied with human-readable interpretation (HRI) for the code content below the code.

Figure 4-1 shows human readable translation in Chinese prior to the single text lines with the values of REF, expiration date, production date, lot number, and serial number. The emblem “UDI” in connection with the Chinese text lines introduces that the code carries the UDI code for China.



Figure 4-1 Example label with HRI, Chinese text lines for introducing the data elements of MA-UDI and QR Code as data carrier

Figure 4-2 shows human readable translation in Chinese and pictograms prior to the single text lines with the values of REF, expiration date, production date, lot number, and serial number. The emblem “UDI” in connection with the Chinese text lines introduces that the code carries the UDI code for China.



Figure 4-2 Example label using QR Code as data carrier and being applied with HRI, human translation lines in Chinese and pictograms prior to the single data values.

Figure 4-3 shows QR Code with HRI and also human readable translation and short titles in English for REF, production date, lot number, and serial number data.



Figure 4-3 Example label applied with HRI, human translation lines in Chinese and short titles in English prior to the single data values

Figure 4-4 shows a MA-UDI label like Figure 4-3 but applied with a Data Matrix data carrier (ISO/IEC 16022).



Figure 4-4 Example label using Data Matrix data carrier

Appendix I – Bibliography

YY/T 1630-2018 Fundamental requirements for unique device identifier

YY/T 1681-2019 Basic terms of unique identification system

YY/T 1879-2022 Creation and placement of unique device identifier

YY/T 1942-2024 Form and content of the unique device identifier

YY/T 1943-2024 UDI implementation and application in medical device package levels

ISO 3166-1 Codes for the representation of names of countries and their subdivisions — Part 1: Country code

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO/IEC 646 Information technology — ISO 7-bit coded character set for information exchange

ISO/IEC 15415 Information technology — Automatic identification and data capture techniques -
- Bar code print quality test specification — Two-dimensional symbols

ISO/IEC 15416 Information technology — Automatic identification and data capture techniques
— Bar code print quality test specification — Linear symbols

ISO/IEC 15417 Information technology — Automatic identification and data capture techniques
— Code 128 bar code symbology specification

ISO/IEC 15424:2025 Information technology—Automatic identification and data capture
techniques—Data carrier identifiers (including symbology identifiers)

ISO/IEC 15459-2 Information technology — Automatic identification and data capture
techniques — Unique identification - Part 2 Registration procedures

ISO/IEC 16022 Information technology — Automatic identification and data capture techniques
— Data Matrix bar code symbology specification

ISO/IEC 18004 Information technology — Automatic identification and data capture techniques
— QR Code bar code symbology specification

ISO/IEC 21471 Information technology — Automatic identification and data capture techniques
— Extended rectangular data matrix (DMRE) bar code symbology specification

ISO/IEC 29158, Information technology — Automatic identification and data capture techniques
— Direct Part Mark (DPM) Quality Guideline

DB12/T 1016-2020 General requirements for design and implementation of medical device
traceability system

Appendix II – Introduction of ZIIOT and partnerships

2.1 ZIIOT Research Institute-MA code issuing agency

ZIIOT Research Institute is an international code issuing agency accredited according to ISO/IEC 15459-2. The Issuing Agency Code (IAC) is "MA". It is responsible for the management and maintenance of MA identification system and code issuance, and provides global MA identification root resolution services.

ZIIOT Research Institute is one of the UDI code issuers recognized by NMPA in China. It cooperates with international organizations such as European Data Council Institute (EDCi) and the Health Industry Business Communications Council (HIBCC) to complete the UDI cooperation and communications.

2.2 UTC Global-Global MA code operation organization

Accredited and authorized by ZIIOT, UTC Global provides global MA identification code issuance and registration services. As the operation organization of the MA code system, it undertakes core mandates, including international unique identification code issuance and the development of an accreditation and evaluation framework.

Serving as the global two-dimensional code service organization for MA identification, UTC Global sets up branch offices across nations to administer relevant regional and industrial affairs.

The UTC UDI Service Platform (<http://udi.idcode.org.cn>) is a global service portal for stakeholders in the medical device industry, maintained and operated by UTC Global. The platform supports the full lifecycle management of MA UDI, covering UDI registration, application, utilization and deactivation, while maintaining real-time data synchronization with national regulatory authorities.

2.3 National code issuing agencies

UTC Global will set up code distribution operations in countries around the world. At present, it has established UTC China and is building national branch distribution institutions such as UTC Korea, UTC India, UTC Canada, UTC Laos and UTC Myanmar, and continues to accept applications from various countries and regions for the establishment of national branch distribution institutions.

2.4 Contact information

For MA identification code and MA UDI manual, please contact the UDI department of ZIIOT:
Address: Room 4018, F4, Building 6#, No.288, Jinjiacun, Fengtai District, Beijing, China
Email: udi@ziiot.org.cn

For MA UDI service, please contact UTC Global,
Email for China UDI: udicn@idcode.org.cn
Email for European UDI: udieu@idcode.org.cn

