securPharm

CODING RULES FOR MEDICINES REQUIRING VERIFICATION FOR THE GERMAN MARKET

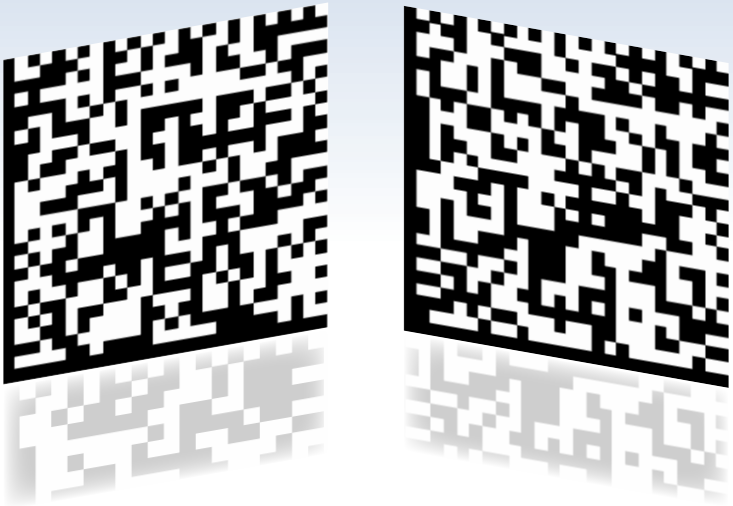
Pursuant to the EU Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) 2016/161

Coding of packaging using Data Matrix Code with the product codes PPN or NTIN and additional data elements

Automatic identification of retail packs in the pharmaceutical supply chain

ASC-Format

IFA CODINGSYSTEM



GS1-Format

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1 Introduction

In accordance with Article 54a para. 1 of Directive 2001/83/EC, which was amended by the so-called EU Falsified Medicines Directive 2011/62/EU (FMD), all medicinal products generally subject to prescription must bear safety features that facilitate specifically the identification of individual packs and the verification of their authenticity. Pursuant to Article 2, para. 2 (b) of the FMD, the member states must implement these provisions for affixing safety features three years after publication of the Delegated Act.

The details with regard to the properties and technical specifications of the safety feature "unique identifier" are stipulated in the Delegated Regulation (EU) 2016/161 of the Commission of 2 October 2015, and published it in the Official Journal of the European Union on 9 February 2016. Now the stakeholders of the legal pharmaceutical supply chain in Germany must implement these requirements by 9 February 2019 at the latest. From this date onward, no products covered by the Falsified Medicines Directive and its Delegated Regulation can be released for sale or distribution without bearing the required safety features.

This Regulation requires a system that ensures the identification and authentication of pharmaceuticals based on end-to-end verification of all medicinal products that bear the safety features.

In light of this situation, the stakeholders listed below established the organisation "securPharm e.V." in order to develop a concept for the operational implementation of the verification rules early on, to set up and test the system, and to continuously improve it:

- **ABDA – Bundesvereinigung Deutscher Apothekerverbände e.V.** (Federal Union of German Associations of Pharmacists)
- **Avoxa – Mediengruppe Deutscher Apotheker GmbH**
- **Bundesverband der Arzneimittel-Hersteller e.V. (BAH)** (German Medicines Manufacturers Association)
- **Bundesverband der Pharmazeutischen Industrie e.V. (BPI)** (German Pharmaceutical Industry Association)
- **IFA Informationsstelle für Arzneispezialitäten GmbH** (German Issuing Agency for Pharmacy Products)
- **PHAGRO | Bundesverband des Pharmazeutischen Großhandels e.V.** (Association of Pharmaceutical Wholesalers)
- **Verband Forschender Arzneimittelhersteller e.V. (vfa)** (Association of Research-Based Pharmaceutical Companies)

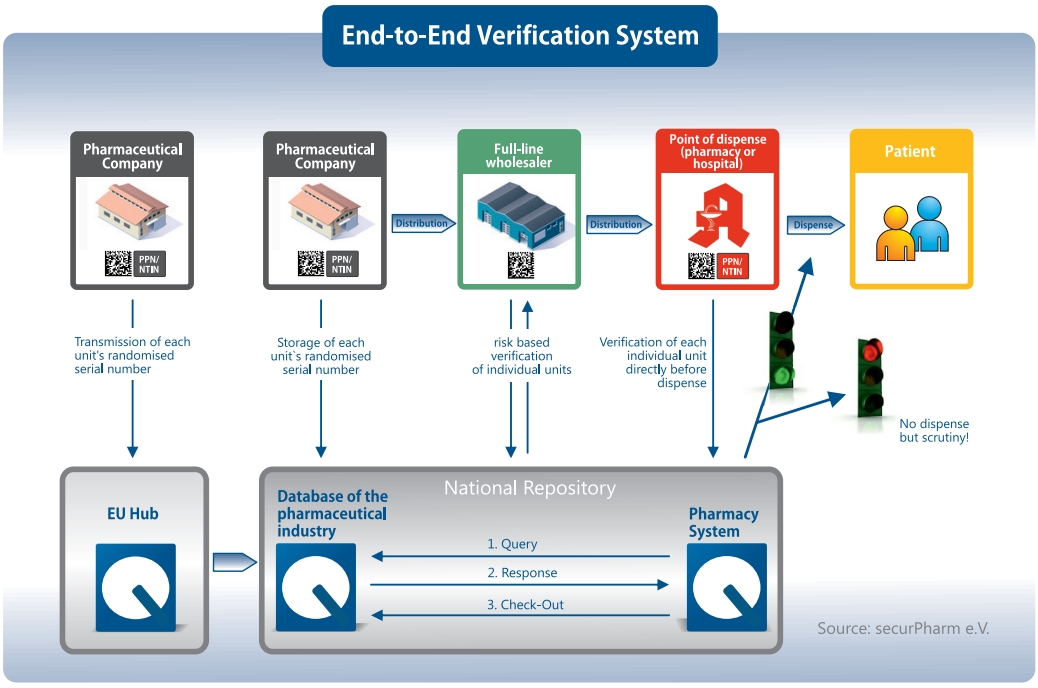

Figure 1: End-to-End Verification System

securPharm is based on a concept in which the technical approach of the system ensures that the stakeholders remain in charge of their data (see Figure 1). The marketing authorisation holders (MAH) upload their package-related data to the database system of the pharmaceutical industry (ACS-MAH-System). To run the ACS-MAH-System, the associations of BAH, BPI and vfa have established ACS PharmaProtect GmbH as the operating company. Verification inquiries from the pharmacies are bundled via a centralised pharmacy system and sent to the ACS-MAH-System in anonymised form. The pharmacy system is operated by *Avoxa – Mediengruppe Deutscher Apotheker GmbH*. Wholesalers also conduct their verifications via the centralised pharmacy system. This anonymization of the verification inquiries from the pharmacy system ensures mutual data confidentiality and leaves the responsibility with the process operators. It has also created the most favourable conditions in terms of efficiency of organisational costs, investments and operating costs.

Since 2013, pharmaceutical companies have been able to use securPharm and practice their own processes. With securPharm, the National Medicines Verification System (NMVS) has been created for Germany. As such, it serves as a partner within the safety network in Europe provided by the European Medicines Verification Organisation (EMVO).

As a core element for verification, the FMD requires that each package shall bear a so-called unique identifier. To ensure identification of the unique identifier on the pharmaceutical packages, this specification includes the requirements of the legislature and supplements it with the necessary technical details.

The editor points out that these "Coding Rules" were generated to the best of his knowledge based on the current findings at the time of printing.

Due to open legal and technical questions and the possibly required adjustment of social law requirements and others, future modifications and adjustments cannot be excluded, which means that this right must be expressly reserved.

For additional information on securPharm, please visit www.securPharm.de.

2 Scope

Since verification takes place in a networked system between various stakeholders in a so-called open system, mutual technical coordination is a mandatory prerequisite for smooth operations.

It is for this purpose that these coding rules describe the technical specifications of the unique identifier for pharmaceuticals that are subject to labelling and that are to be placed on the German market. They must be used by the MAHs who label pharmaceuticals as well as the stakeholders who have to perform the verification of the unique identifier. The latter are primarily pharmacies and wholesalers. Their system providers must observe and implement these specifications.

This document contains the special features of the product code defined for the German market. Coding, code content, code size and print quality as well as the associated labelling of the pharmaceutical packages are described in detail.

Note: The rules set out in this document may deviate in some parts from the current GS1 specifications. However, in such cases the rules set out in this document take precedence.

Transport logistics and the associated external packaging are outside the scope of this specification. The underlying ISO coding standards for the securPharm project allow the operator to integrate data and the system of the Pharmacy Product Number (PPN) or National Trade Item Number (NTIN) into higher-level standard logistics and aggregation systems (ISO 15394).

Furthermore, these coding rules do not describe the following:

- the necessary information technology (IT) processes as part of verification; and
- the anti-tampering device required in the FMD.

3 Technical information concerning verification – overview

3.1 Serial number rules

The serial number required for verification is a numeric or alphanumeric sequence of a maximum of 20 characters generated by the marketing authorisation holder (MAH). To make matters as difficult as possible for forgers, these serial numbers assigned by the MAH must be generated by a deterministic or non-deterministic randomisation algorithm. In any case, the probability of deriving a serial number must be lower than 1: 10,000. In addition, the randomised serial number in combination with the product code based on the PZN must be unique for each pharmaceutical pack for a period of at least one year after the pack's expiry date or at least five years after the pharmaceutical has been released for sale or distribution (the longer time period shall apply).

Reusing serial numbers represents a potential error source and is therefore not recommended.

3.2 Data transfer to the securPharm System

For the verification process, the MAH transfers the package data to the ACS-MAH-System of securPharm. These contain the following key data elements:

- product code (either as PPN or NTIN)
- serial number
- batch number
- expiry date

Apart from the above-mentioned key data elements, the MAH must also transfer additional information, e.g. pursuant to Art. 33 para. 2 lit. (f) of the Delegated Regulation, the manufacturer who affixed the safety features.

In reference to the corresponding PZN, the required product master data are currently directly transmitted to the ACS-MAH-System[1] via the information services of the IFA.

The verification process is available for those products the MAH has reported to IFA via the change service. The upload of product master data from the IFA system to the ACS-MAH-System also depends on this report.

The prerequisite for participation in the national verification system is a concluded user agreement with ACS. An early connection is important in order to practice the corporate processes and to identify and exclude possible internal error sources.[2]

For more detail information on the organisational and technical connection to the ACS-MAH-System, please visit http://www.pharmaprotect.de/en/.

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1 The statements on product master data initially apply to the direct connection to the national system of ACS. The concept will be revised as soon as details concerning the connection to the HUB are available.

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2 For companies just starting their conversion to the new safety features, we strongly recommend connecting early on. By doing this, they will benefit from an exchange of experience with other market participants and from the support by experts from securPharm and ACS.

4 Coding agreements

4.1 General

In accordance with Article 4 of the Delegated Regulation, the unique identifier includes the following data elements:

- product code
- serial number
- batch number
- expiry date

An additional element mentioned in Article 4 is the national reimbursement number. For pharmaceuticals destined for the German market, it is included in the product code in form of the PZN (see ***Chapter 4.2***) and therefore does not need to be listed as a separate fifth element pursuant to Article 4 (e) of the Delegated Regulation.

Coding is done in the Data Matrix Code (DMC) in accordance with ISO/IEC 16022 (see ***Chapter 6.1***) and the data structure and syntax pursuant to ISO/IEC 15418 and ISO/IEC 15434 (see ***Chapter 5***).

This ensures machine readability of these data elements and creates the technical prerequisite for the implementation of the EU Falsified Medicines Directive and additionally expected legal requirements for the verification of pharmaceutical packages.

At the same time, the requirements from Article 5 “Carrier of the unique identifier” of the Delegated Regulation are met.

In order to comply with Article 4 lit. (d) of the Delegated Regulation, an unambiguous product code on a Europe-wide scale is needed. In order to meet this requirement in Germany the Pharmacy Product Number (PPN) is used as product code for verification. In the Data Matrix Code, the product code can be represented either in the format of a PPN or of a National Trade Item Number (NTIN). Both formats can be generated from the eight-digit (German) PZN. The marketing authorisation holder can choose between the two above-mentioned formats of the product code.

Existing databases and software systems can algorithmically generate a PZN from the PPN or the NTIN or, conversely, a PPN or NTIN from the PZN.

For the retail segment, the PZN will remain the relevant article number and it will continue to be used for reimbursement and legal pharmaceutical concerns. As a result, existing processes will be preserved without change.

Interoperability with other numeric systems, e.g. GTIN (with GS1 as the issuing agency in charge) or HIBC (with EHIBCC as the issuing agency in charge) is reliably ensured by the joint basis of international standards. The next two chapters briefly describe the properties and methods for generating the PPN and the NTIN.

4.2 Pharmacy Product Number (PPN) – Use in Germany

As shown below, the PZN is embedded into the globally unambiguous format of a PPN:

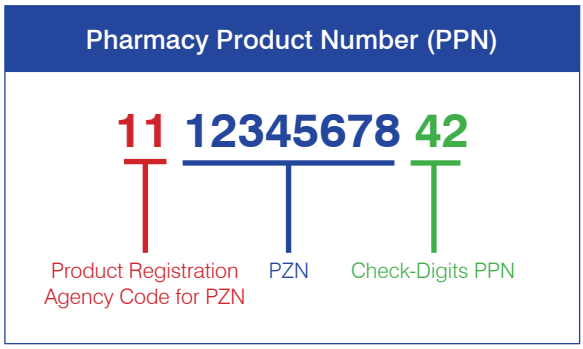


Figure 2: Generation of the PPN

The PPN consists of three parts that are highlighted in red, blue and green. The "11" stands for a Product Registration Agency Code (PRA Code or PRAC). This code is managed and assigned by the IFA. The "11" is reserved for the PZN. The national article number follows after the "11" and is represented in blue. This is the unmodified PZN (PZN8). The subsequent digits (shown in the figure in green) form the two-digit, calculated check number across the entire data field (including the "11"). Together with the PZN represented in this example a value of "42" is resulting.

For more detailed information on the PPN and the PPN-generator, please see http://www.ifaffm.de/en/ifa-codingsystem/pzn-to-ppn.html and the document "Data Matrix Code for retail packs" at http://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html.

4.3 National Trade Item Number (NTIN) – Use in Germany

As shown below, the PZN is embedded into the globally unambiguous format of a NTIN:

Figure 3: Generation of the NTIN

The NTIN consists of three parts that are highlighted in red, blue and green. The "4150" is the prefix assigned for the PZN by GS1 Germany. The unmodified PZN, represented in blue, follows (PZN8). The last digit (shown in the figure in green) represents the check digit across the entire data field. In addition, the NTIN must be prefixed by a "0" to make it to a 14-digit format for this application.

Detailed information on the NTIN and the generation of the check digit can be found in the NTIN Guideline of GS1 (https://www.gs1-germany.de/fileadmin/gs1/basis_informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf).

4.4 Codes and data content on pharmaceutical packages

The coding of the PZN within Code 39 and other codes such as the EAN-13 will be kept on retail packages until further notice.[1] This ensures retention of established processes. By products subject to mandatory verification the Data Matrix Code must be affixed additionally.

For all other products the affixement of a Data Matrix Code is optional. In addition to the PPN/NTIN other elements can be included in the Data Matrix Code. Exception: a serial number is not allowed for products not being subject to mandatory verification.

The basic versions are described below:

	Code 39[1]	Content Data Matrix Code			
	PZN	**PPN/NTIN**	**SN**	**LOT**	**EXP**
Medicinal product subject to mandatory verification	√	√	√	√	√
Medicinal product not subject to mandatory verification	√	√	Not allowed	optional	optional

Figure 4: Variations of application in coding

1 According to the German Social Code Book V (SGB V), indication of the PZN within the PZN code remains obligatory for the time being.

The Delegated Regulation allows that additional one- or two-dimensional codes be affixed to the package, as long as they do not contain the unique identifier that serves to verify the authenticity or identity. As a result, it may be possible as part of the individual marketing authorisation to affix codes that contain additional information or reference other sources, e.g. a uniform resource locator (URL). However other codes may affect process security and should be limited to an absolut necessary minimum.

4.5 Multi Market Packs

Multi market packs (MMPs) are retail packs that can be dispensed in multiple countries with a certain layout. Within the “blue box”, they bear several national product codes for reimbursement and merchandise management purposes as well as various country-specific pieces of information.

For MMPs that are subject to mandatory verification, it is imperative that a product code be defined that can be used for all countries in which the pharmaceutical in question must be verified. Together with the associated serial number and all other pieces of information, this product code is uploaded via the HUB to all national verification systems. When the pharmaceutical is dispensed, the status of the pack in question is synchronised via the HUB in all national verification systems concerned.

Each country determines which national number apart from the product code must be incorporated in the Data Matrix Code. For pharmaceuticals destined for the German market, it is mandatory to include the PZN in the Data Matrix Code. This can be done directly within the product code as described in ***Chapter 4*** or as an additional element, if the product code is assigned to another country.

Coding details are described in ***Chapter 5.3***.

Figure 5: Multi market pack

4.6 Clinic packs

In principle clinic packs are coded identically to pharmacy retail packs. Clinic packs consisting of clinic components[1] represent a special scenario. In this case, the clinic pack, not the clinic component, represents the retail pack. As a result the unique identifier must be affixed to the clinic pack, not the clinic component.

Clinic components may bear a DMC, e.g. for logistical reasons, but the data elements must not be transmitted to the ACS-MAH-System or used for verification (see table below).

	Pharmacy retail packs	Clinic packs	Clinic packs with so-called clinic components [1]	
				
Pack contents	Single objects (blister, coated tablets, vials, …)	Single objects (blister, coated tablets, vials, …)	Individual packs, so-called clinic components, that are combined in a bundle or different outer packaging to form a clinic pack	
IFA article type	Retail pack	Clinic pack	Clinic pack	Clinic component
PZN in the Code 39 (bar code)	√	√	√	√
Data Matrix Code - content	obligatory - product code - serial number - batch number - expiry date	obligatory - product code - serial number - batch number - expiry date	obligatory - product code - serial number - batch number - expiry date	optional - product code - batch number - expiry date
ACS-MAH-System	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	–
Object of verification	√	√	√	–

Figure 6: Overview of clinical packs

1 The term clinic component describes a pack whose layout is identical to the retail pack but which cannot be sold independently. A PZN has been assigned to the clinic component for identification. The PZN of the clinic component refers to the PZN of the clinic pack. Clinic components combined in a bundle or a different outer packaging form a clinic pack to which a PZN is assigned, that is relevant for wholesale and retail purposes.

5 Data content and requirements

5.1 Identifiers and structures

This chapter defines the data identifier / application identifier to be used and the characteristics of the data elements. The data identifier / application identifier in accordance with international standard ISO/IEC 15418 are used (references ANSI MH10.8.2; Data Identifier and Application Identifier Standard). IFA uses the ASC MH10 data identifier (DI) and GS1 works with the application identifiers (AI).

Typically, the standards leave the characteristics of the data elements open. Therefore, this document defines the data type, length and character set in question in a manner that is binding for all market participants (see ***Chapter 5.2***). The use of one of the following two versions is allowed for structures and identifiers:

A **Structure in format 06 according to ISO/IEC 15434 and ASC MH10 Data Identifier (DI) according to ISO/IEC 15418 (ANSI MH10.8.2)** For details, see IFA's specification: http://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html (document "Data Matrix Code on retail packs")

B **System Identifier "FNC1" and Application Identifier (AI) according to ISO/IEC 15418** For details, see GS1's specification: https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/

A summary of the usable data identifier /application identifier as well as the permissible data types, character sets and data lengths for the data to be coded is presented in Appendix A.

Data identifier / application identifier that are not used in this specifications but follow the syntax of MH10.8.2. should be correctly issued in the applications and result in defined conditions.

This must not jeopardize the scan process and the associated data capture. The specified data structures must not be violated by such extensions.

If any additional data designators are employed for joint usage by the market participants, securPharm will add these to the data designators described in ***Chapter 5.2*** of the Coding Rules and provide a clear description of their application.

5.2 Single market packs – Data elements and corresponding data identifiers / application identifier

5.2.1 Product code

- **Data Identifier (DI): „9N"**
- **Application Identifier (AI): „01"**

The product code is used for product identification, either in the form of the Pharmacy Product Number (PPN) or the National Trade Item Number (NTIN). The product code is the leading data element in the DMC, all other data elements refer to it. The product code contains the PZN, which can be extracted from it (see ***Chapter 4.2*** and ***Chapter 4.3***).

The expanded eight-digit PZN must be used.

Example:

Format	DI AI	Data
ASC	9N	110375286414
GS1	01	04150037528643

5.2.2 Serial number

- **Data Identifier (DI): „S"**
- **Application Identifier (AI): „21"**

The serial number is generated by the marketing authorisation holder and represents the corresponding data element of the unique identifier. It is mandatory for the verification process. The serial number must not be affixed to pharmaceuticals for which verification is not mandatory.

Example:

Format	DI AI	Data
ASC	S	12345ABCDEF98765
GS1	21	12345ABCDEF98765

The usable characters are described in ***Appendix A***.

5.2.3 Batch number

- **Data Identifier (DI): „1T“**
- **Application Identifier (AI): „10“**

The batch number is generated by the marketing authorisation holder, thereby representing the corresponding data element for the DMC. Predefined special characters can be used to distinguish partial/sub-batches (see *Appendix A*).

Example:

Format	DI AI	Data
ASC	1T	12345ABCD
GS1	10	12345ABCD

5.2.4 Expiry date

- **Data Identifier (DI): „D“**
- **Application Identifier (AI): „17“**

The expiry date is generated by the marketing authorisation holder, thereby representing the corresponding data element for the DMC.

The expiry date has the format “YYMMDD”.

YY = two-digit year number
Since the expiry date can only be in the future, the dates are for the 21st century (2000-2099).

MM = Numerical representation of the month (01–12)
DD = Day

a) Expiry date listing the day, month and year (DD = 01–31)
b) Expiry date listing the month and year (DD = 00)

Example: Expiry date in June 2021.

Format	DI AI	Data
ASC	D	210600
GS1	17	210600

Example: Expiry date on 30 June 2021.

Format	DI AI	Data
ASC	D	210630
GS1	17	210630

This example presents the possibility of indicating an expiry date that is exact to the day.

Note: In ANSI MH10.8.2, “D” is defined as the date in general. In the context of the PPN, the date “D” is necessarily the expiry date. For other date listings, such as the date of production, other identifiers must be used. For the production date, this would be the DI “16D” or the AI “11” respectively.

5.2.5 Additional data elements – Sample URL

The above-mentioned data elements are obligatory for meeting the requirements of the Delegated Regulation. Article 8 of the Delegated Regulation allows the integration of additional data elements, if this is permitted by the authority in charge pursuant to Title V of Directive 2001/83/EC or Section 10 para. 1, clause 5 of the German Medicinal Products Act (AMG).

For example, a URL can be integrated into the code:

Format	DI AI	Data
ASC	33L	http://Example.de
GS1	8200	http://Example.de

It must be noted that long URLs considerably enlarge the code and the scan rate could deteriorate accordingly.

5.3 Multi market packs – Data elements and associated data identifiers

5.3.1 General

As for single market packs, the Data Matrix Code for multi market packs also includes the unique identifier and the product code included in it is used for verification.

One special characteristic is the fact that the product code does not necessarily represent the country-specific identification of a pharmaceutical completely and that additional national item or reimbursement numbers can therefore also be included in the code in addition to the unique identifier. According to the country-specific provisions and trade requirements, these supplementary pieces of information must also be included in the Data Matrix Code. This makes it possible to capture the data relevant for verification as well as the additional numbers for country-specific identification of the pharmaceutical with a single scan.

The user software extracts from the code the item or reimbursement numbers known to the merchandise management system, which are required for identification and further handling. This process is analogous to the present approach during the sequential scanning of linear barcodes.

In the **GS1 format,** the unique identifier of the product code is provided by the **AI (01)** and the **DI (9N)** in the **ASC format.** It is recommended to code the product code as the first data element.

If necessary, the higher data volume can be managed via the additionally defined Data Matrix rectangular codes (see ***Chapter 6.2***).

The details for coding country-specific identification numbers is described below. All other specifications from ***Chapter 5.1*** and ***Chapter 5.2*** also apply to the MMPs.

5.3.2 Country-specific identifier in GS1 format:

The product code is marked by the AI (01). The additional country-specific numbers for identification of the pharmaceutical are marked by the AI (71x) assigned to the so-called NHRN.

For MMPs that are marketable in Germany, the German PZN with the AI (710) as NHRN and the GTIN of one of the other markets as the product code must be represented in the Data Matrix Code.

Additional markets must be labeled in the Data Matrix Code with the NHRN in question. The country-specific requirements must be taken into account.

Example of an MMP in the GS1 format (AIs)

Format	AI	Daten
GS1	01 [1]	08701234567896
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	210600
GS1	710 [2]	12345678
GS1	711 [3]	91234567

1 Product code (PC) GTIN

2 Additional country-specific product identification via NHRN, example with a German PZN

3 Additional country-specific product identification via NHRN, example with a French CIP

5.3.3 Country-specific identifier in ASC format:

The product code is marked by the DI (9N). If the additional country-specific number for identification of a pharmaceutical is available in the format of a GTIN or NTIN, it is labeled with the DI (8P).

If there are several country-specific numbers in the format of a GTIN or NTIN, the additional data identifiers (8P) are included in the code multiple times.

Example of an MMP in ASC format (MH10 DIs)

Format	DI	Daten
ASC	9N[1]	111234567842
ASC	S	1234567890ABCD
ASC	1T	1234AB
ASC	D	210600
ASC	8P[2]	08701234567896
ASC	8P[3]	03400912345676

1 Product code (PC) PPN, example with the German PZN “12345678”

2 Additional country-specific product identification via GTIN

3 Additional country-specific product identification via NTIN

If the additional country-specific characteristic for product identification is available in a format that deviates from the GTIN or NTIN, the corresponding MH10 – DI assigned to the format in question pursuant to the ANSI standard must be used, e.g. (25P) for HIBC.

The implementation of this version must be coordinated with the EMVO. Until then, the technical implementation within the HUB is pending. securPharm will separately inform as soon as the implementation has been completed.

6 Marking with code and human readable text

6.1 Symbology

This chapter describes the code requirements for human readable form (clear text) and elements such as the code emblem. The data carrier used or the symbology is the data matrix pursuant to ISO/IEC 16022. Error correction is done according to ECC200. The other error correction methods (ECC000 to ECC140) must not be used. If a consistent matrix size is to be printed at all times, padding characters may have to be inserted.

6.2 Matrix size

Typically, the matrix size should not exceed 26x26 or 26x40 modules. Smaller matrix sizes are allowed provided the capacity for the data to be coded is sufficient.

Depending on the package layout and the technical printing conditions, square or rectangular DMCs can be used. For rectangular codes, the additionally specified versions in accordance with DIN 16587:2015-11 can also be used. See the tables below for typical matrix sizes and their characteristics:

Square symbols

Matrix size		Dimension (mm)			Data capacity	
Rows	Columns	Typical X = 0.35	Min X = 0.25	Max X = 0.615	Numeric	Alphanumeric
22	22	7.7	5.5	13.5	60	43
24	24	8.4	6.0	14.8	72	52
26	26	9.1	6.5	16.0	88	64
32	32	11.5	8.2	20.3	124	91

Rectangular symbols

Matrix size		Dimension (mm)			Data capacity	
Rows	Columns	Typical X = 0.35	Min X = 0.25	Max X = 0.615	Numeric	Alphanumeric
16	36	5.6 x 12.9	4 x 9.2	9.8 x 22.7	64	46
16	48	5.6 x 17.1	4 x 12.2	9.8 x 30.1	98	72
24	48	8.4 x 17.1	6.0 x 12.2	14,8 x 30,1	160	118
26	48	9.1 x 17.1	6.5 x 12.2	16,0 x 30,1	180	133

X = Module size in mm

The codes in the last two rows of the table rectangular symbols originate from DIN 16587:2015-11 Information technology – Automatic identification and data capture techniques – Data Matrix Rectangular Extension. It is applied to assimilate these and more rectangularmatrix dimensions to ISO standards. It should be noted that currently (date of issue of these coding rules) these new variants of the Data Matrix Code can not be read at all points of verification. Those have to adapt gradually and must be able to read these codes until the application of the Delegated Regulation.

6.3 Code size and quiet zone

The code module size may vary between 0.25 and 0.615 mm. The technical properties of the scanners used must be adjusted to this area of module sizes. Within this area, the module sizes can be scaled as needed in consideration of the print quality (see ***Chapter 7***) and the printing systems to be used.

The module size describes the size of one matrix cell (see ***Chapter 6.2***). Typical module sizes range from 0.33 to 0.45 mm.

The areas immediately surrounding the code must be kept free of printing. This area, the so-called quiet zone, should be at least three modules wide to ensure an acceptable initial reading rate of this application.

6.4 Positioning of the Data Matrix Code

There are no specific rules concerning code positioning. The manufacturer determines the position based on the package layout and the printing conditions.

This also applies for centrally authorised medicines, whereby the DMC must be placed outside the “blue box”.

6.5 Data Matrix Code emblem

The “PPN” emblem of the Data Matrix Code indicates to the points of verification the code, which is used for automatic identification of the product code and other data, regardless of which format is used to embed the PZN in the DMC. The emblem “PPN” is used as long as another uniform emblem is specified and agreed upon at international level.

Figure 7: Emblem of the code

During a transition periode the emblem may be omitted. As a result, the marketing authorisation holder has more freedom during the conversion processes.

Affixing the emblem is mandatory for packages that bear a second 2D code.

There are various possible versions and details for the graphical representation of the emblem (see ***Appendix B***).

The emblem can be affixed through both primary and inline printing. The minimum spacing to the code (quiet zones) must be observed.

6.6 Human readable information (clear text)

The PZN is the key element of the retail pack. According to the currently effective regulations, the PZN must be placed in clear text with the Code 39 (see the specification for the PZN at http://www.ifaffm.de/en/ifa-codingsystem/encoding-pzn-code39.html).

In the furture, apart from the elements of PZN, batch number and expiry date, marketing authorisation holders will have to place the product code and serial number in a human-readable format to the pack. To ensure readability, the explanations of the *„Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use“* (the so-called EU Readability Guideline) must be observed.

Product code and serial number:
If the packaging dimensions allow, the clear text information of the product code and the serial number shall be located next to the two-dimensional barcode that contains the unique identifier.

If the product code and the serial number are represented in two lines below each other, the first line must present the product code and the second the serial number.

The PPN or NTIN contained in the code must be used as the **product code**. For labelling, the abbreviation “**PC:** ” is used as a prefix.[1] Since the product code is fixed for the product layout in question, this can also be affixed in primary printing.

The **serial number** must be preceded by the abbreviation „**SN:** “.[1]

1 Mind the blank after the colon.

Exceptions according to the Delegated Regulation

If the sum of the two longest dimensions of the packaging equals or is less than 10 cm, the clear text representation of the product code and serial number can be omitted.

Batch number and expiry date:
The pharmaceutical law requirements for labelling shall apply to the clear text information of the batch number and the expiry date. The abbreviation "**Ch.-B.:** " must be selected for the **batch number**.[1]

The **expiry date** must be supplemented with the German phrase „**verwendbar bis** " ("use before "). For containers with a nominal fill quantity of up to 10 millilitres and for single-dose ampoules, the phrase can be appropriately abbreviated (e.g. "**verw. bis** ") pursuant to the German Medicinal Products Act.[2]

Example PPN:

Example NTIN:

1 Mind the blank after the colon.

2 Mind the blank after "bis".

7 Quality control of the Data Matrix Code

The basic prerequisite for a usable code is correct coding of the data and compliance with predefined print quality. Both can be ensured through quality assurance measures.

When checking the quality of a code, it must be basically distinguish between code scanning and check print quality. Code scanning verifies the code content, thereby ascertaining the interpretation of the data content and the correctness of data. In this respect, the stipulations of the previous chapters and the following information must be considered:

In digital printing, each print must be considered individually. Therefore, the code content of each package must be verified via code scanning.

Determination of print quality:
Print quality is the physical quality of printing. The determination of and compliance with a predefined minimum print quality safeguards a high initial reading rate. This purpose is served by the explanations in this chapter. Further details are presented in ***Appendix D***.

Pursuant to the Delegated Regulation, print quality must be judged according to certain parameters (see ***Appendix D.5***).

The MAH must determine the minimum print quality for code readability along the entire supply chain and during the usage cycle[1] and establish threshold values for the parameters mentioned in ***Appendix D.5.***

More practicable is the possibility provided in Article 6 para. 4 of the Delegated Regulation that the requirements are considered met for a print quality of at least 1.5 pursuant to ISO/IEC 15415 (see side table). The MAH, has to take into account the wear and tear of printing.

1 Minimum time period pursuant to the Delegated Regulation: One year past the expiry date or five years after releasing the pharmaceuticals for sale or distribution. The longer time period is relevant.

Quality levels pursuant to ISO/IEC 15415:

ISO/IEC grade	ANSI grade	Ø for multiple measure-ments*	Meaning
4	A	3.5 – 4.0	Very good
3	B	2.5 – 3.49	Good
2	C	1.5 – 2.49	Satisfactory
1	D	0.5 – 1.49	Adequate
0	F	Less than 0.5	Fail

* Multiple measurements are no longer required in the current version of ISO/IEC 15415 (Dec. 2011). As a result, the minimum requirement of 1.5 always corresponds to ISO/IEC category 2.

Conventional scanners can read codes even below ISO/IEC category 1.5 (ISO/IEC 15415). However, technical variations among conventional scanners are very large.

Users must select or parameterise scanners in such a manner that codes of ISO/IEC grade 0.5 (ISO/IEC 15415) are still readable.

Based on this determination, printing with a quality lower than 1.5 meets the requirement of the Delegated Regulation. During this determination, the manufacturer must also take into account the wear and tear of printing.

However, to achieve a very high initial reading rate, the marketing authorisation holder must not permanently go below the 1.5 requirement (according to ISO/IEC 15415).

In practice, a control by 100% scanning check (with or without inline pseudo grading) is frequently performed with inline systems in combination with a metrological sample inspection, for quality assurance.

Information on sample inspection:[2]

Quality assurance at pharmaceutical manufacturers typically works with sampling plans. These determine how many inspections must pass the test and usually also allow a certain quantity of samples that fall below the minimum quality.[3] The marketing authorisation holder is responsible for defining the sampling plans.

Information on the measuring devices:

Measuring devices (see ***Appendix D.3***) that work in accordance with ISO/IEC 15415 must be configured by the user for the application in question. The number of parameters varies depending on the measuring device manufacturer.

The present coding rules are the user specification according to ISO/IEC 15415[4] and therefore the requirement for the correct configuration of a measuring device for print quality inspection of a Data Matrix Code.

To obtain comparable, valid measuring results, the following applies:

The minimum quality must be determined under red light (660 nm), a synthetic aperture of 80% of the code's module size and four-sided lighting under 45°. Additional details are presented in ***Appendix D.4***.

2 The ISO/IEC 15415 standard, which is listed in the Delegated Regulation in Article 6 para. 4, includes the sampling system in Chapter 5.1 "General": "Information on sampling plans may be found in the following: ISO 3951-1, ISO 3951-2, ISO 3951-3, ISO 3951-5 or ISO 2859-10". As a result, the system for sample inspections implicitly becomes part of Article 6 para. 4 of the Delegated Regulation, since Chapter 5.1 is located in the normative and therefore binding part of ISO/IEC 15415.

3 In an extreme scenario, a code in lesser quality could result in a non-scan.

4 ISO/IEC 15415 stipulates the rules for quality determination. The standard requires that the user specification has to define the type of light, lighting arrangement and synthetic aperture for measurements.

8 Interoperability based on XML standards

Appendix C presents a standard to be preferentially used that is based on general XML standards and includes a neutral description of the data/application identifiers. This facilitates an open data exchange as described in Figure 8, independent of symbols and data structures.

The XML nodes defined in *Appendix A* are for the standardized XML data exchange.

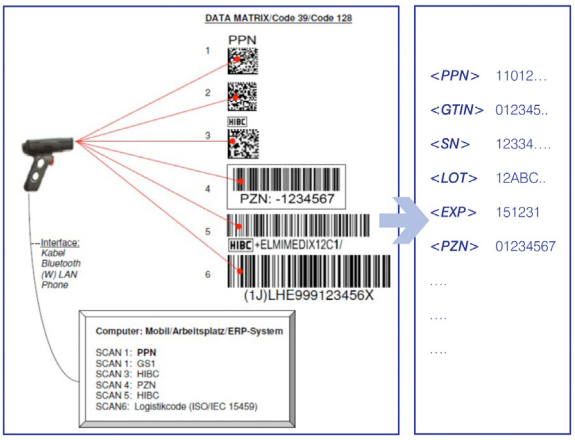


Figure 8: XML-based data exchange between scanner and system

Appendix A
Overview and reference of identifiers

The table below specifies the characteristics of the individual data/application identifiers:

Data elements	XML node	DI	AI	Data type	Data format	Character length	Character set
Pharmacy Product Number (PPN)	<PPN>	9N		AN	—	4–22	0–9; A–Z no special characters, no use of lowercase letters, no national characters
National Trade Item Number (NTIN)	<GTIN>	8P	01	N	—	14	0–9
Serial number	<SN>	S	21	AN	—	1–20	Numeric or alphanumeric characters), no national characters
Batch number	<LOT>	1T	10	AN	—	1–20	Numeric or alphanumeric characters), no national characters
Expiry date	<EXP>	D	17	Date	YYMMDD	6	0–9

Note:
Details for the data elements are located in ***Chapter 4*** and ***Chapter 5*** of this document, for example the specifica of the expiry date.

Recommendations to the marketing authorisation holders regarding the character set for serial number and batch number:

a) The character string should only include either uppercase or lowercase letters of the Latin alphabet.

b) To avoid human reading errors and depending on the font used and print quality, the marketing authorisation holder should exclude characters that are prone to be mistaken for each other. These include e.g.: i, j, l, o, q, u and I, J, L, O, Q, U.

c) While some special characters are technically processed,[1] they should not be used because the risk of misinterpretation is very high. A misinterpreted code results in a package being unable to be verified, thereby making it ineligible to be dispensed.

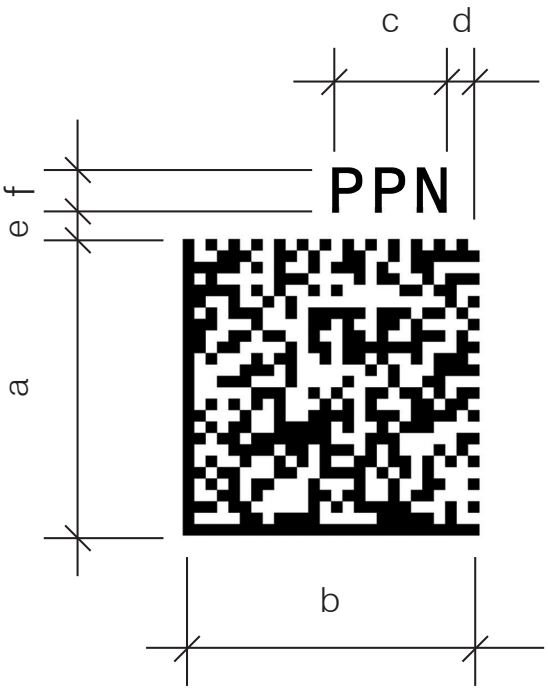
If separating characters are necessary within a batch number, the use of a hyphen "-", underscore "_" or full stop (".") is recommended.[2]

1 The special characters with the decimal ASCII code values of 35 (#), 36 ($), 64 (@), 91 ([), 92 (\), 93 (]), 94 (^), 96 (`), 123 ({), 124(|), 125 (}), 126 (~) and 127 (¦) and all control characters (ASCII code value 00-31) are excluded from technical processing. In principle, all ASCII characters with a decimal value of more than 127 are excluded. The technically processed characters are in accordance with „GS1 AI encodable character set 82" (GS1 General Specifications, section 7.11 (figure 7/11-1)).

2 The use of the full stop character is particularly recommended, since its location is identical in German and English keyboards. If the wrong language is selected for the keyboard scanners used, the risk of misinterpretation does not exist per se.

Appendix B
Code emblem

The string “PPN” in the font “OCR-B” has been defined as the PPN-Code Emblem. The graphical representation is to be found in the following sketch:



Nominal dimensions:

a: results from the chosen module and matrix sizes

b: for a square code a = b; for rectangular – depends on chosen module and matrix sizes

c: 0,4 * a

d: *)

e: results from the required quiet zone *) (Quiet zone refer to ***Chapter 6.3***)

f: results from the font type and dimension c

*) The dimensions d and e should be chosen so that the code is associated with the emblem.

Tolerances: The tolerances can be freely determined according to the selected printing process.

The following orientations are in principle possible:

In exceptional cases, the emblem can be applied to an adjacent surface.

Appendix C
Interoperability based on XML descriptors (informative)

C.1 General

For manufacturers, wholesalers, pharmacies and clinics, the interoperability of coding is a prerequisite for reading and unequivocal identification of data elements. Integrated interoperability helps to ensure cost-effective processes for the involved parties. The interoperability is based on the joint use of the standards IEC 15434 Syntax for High Capacity Media, ISO/ IEC 15459 Unique identifier, as well as system and data identifier/application identifier according to ISO/IEC 15418.

In order to provide manufacturers and users in the pharmaceutical field an even greater interoperability, in this Appendix, an XML-based standard is described for interpreting the data. This applies both for data transmission to the printer, as well as for data transmission from the code reader to the connected systems.

The Standard set out in this appendix applies only to the data contents, i.e. it does not refer to the layout properties of the code, which include the provisions of the clear text printing and symbology (eg, Data Matrix Code).

During data transmission and in accordance with this standard, the data will be uniformly named using XML nodes independent of the Data Identifiers used in the code. Following layers are formed in the representation of the data:

Application: XML nodes
Data envelope: ISO/IEC 15434 e.g. Format 05, Format 06 etc.
Data structure: Data Identifier (DI) or Application Identifier (AI)
Symbology: e.g. Data Matrix Code

C.2 Data Format Identifier (DFI)

By the transmission of XML-Standard data elements, the properties for the display of the data in the Data Matrix Code are assigned to the Data-Format-Identifier (DFI) and only this is transferred.

The DFI tells us which data envelope according to ISO/ IEC 15434, which Application Identifier (AI or DI) and whether a macro according to ISO/IEC 16022 is used. The DFI instructions can be found in Table 1.

XML Data Format Identifier (DFI)	Format-ID According ISO/IEC 48767	Data-Type Identifier According ISO/IEC 16022	Data Identifier / Application Identifier According ISO/IEC 15418
IFA	06	Macro 06	DI-ASC
GS1		FNC1	AI-GS1

Table 1: Data Format Identifier

The DFI can have the values “IFA” or “GS1” and is transferred in the attribute of the higher level XML node „<Content>“.

C.3 XML-Node for Data

The table below shows the XML-Nodes for data and their mapping to the Data Identifier (DI) und Application Identifier (AI):

Data Identifier			
XML-Node	DI dfi="IFA"	AI dfi="GS1"	Description
<PPN>	9N		product code
<GTIN>	8P	01	product code
<LOT>	1T	10	batch number
<EXP>	D	17	expiry date
<SN>	S	21	serial number

Table 2: XML-Nodes for Data

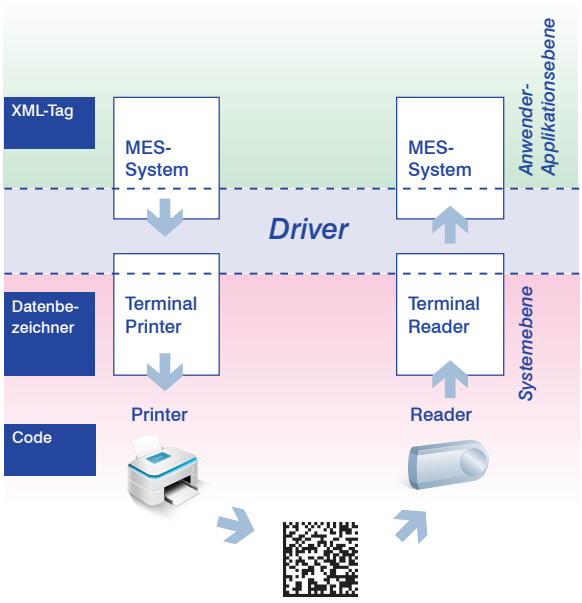


Figure 9: Data transfer based on XML description

The complete list of currently defined nodes is shown in ***Appendix A***. On this technical level of the description there is no difference between NTIN and GTIN. On this basis the comprehensive term GTIN is used.

<Content> envelops the XML nodes <Data> (refer to ***C.4*** and ***C.5***).

From the XML-Data and the „DFI" value contained therein, the printer derives all necessary information to create the Data Matrix Code. This includes the data elements, the DI or AI, the delimiters and the header.

C.4 Implementation

The XML description can be used both in the data transfer to the printer driver, as well as for the data output from the code readers (refer to schematic representation):

The drivers for interpreting the XML description can be part of the higher-levels systems (MES) or the printer and reader. The use of the unified description enhances interoperability and helps to reduce errors. Further, the uncertainty regarding non-printable control character in transmission and interpretation is eliminated in the XML description.

When reading the code, the scanner puts the data content in the XML structure, by using the corresponding XML nodes. By default, data transmission from the code reader to the higher systems only the data is transferred without the "DFI". Output of „DFI" is optional for cases when e.g. the correct use of structures within the code is to be checked.

Generic XML description of data transmission to the printer and from the code reader:

```
<Content dfi="value_dfi">
    <data _ 1>value _ data _ 1</data _ 1>
    <data _ 2>value _ data _ 2</data _ 2>.
    <data _ n>value _ data _ n</data _ n>
</Content>
```

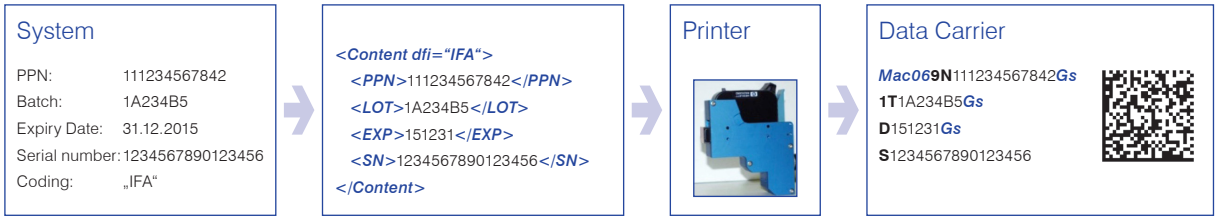
When transferring from the code reader the value of "dfi" is optional.

C.5 Examples

In the following examples the use of the four data elements product number, batch number, expiry date and serial number is illustrated:

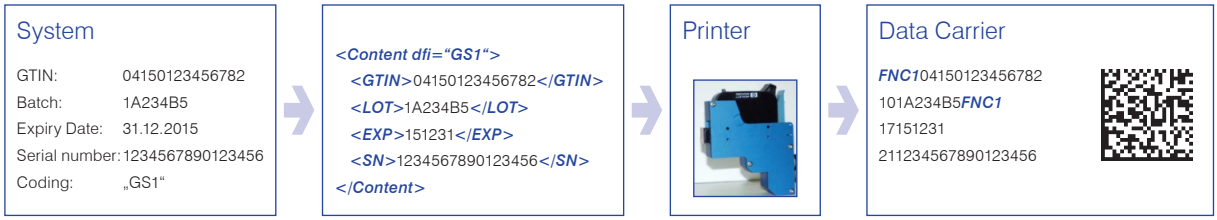
Example 1: Data transfer to printer – ASC-Format

Product Code: PPN | Data Identifier: DI | Data Format Identifier: IFA



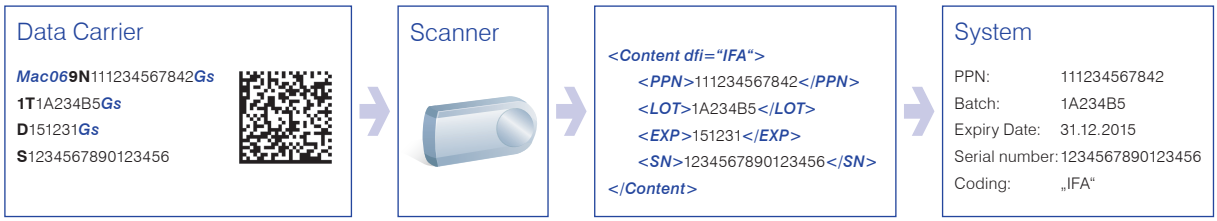
Example 2: Data transfer to printer – GS1-Format

Product Code: GTIN[1] | Data Identifier: AI | Data Format Identifier: GS1



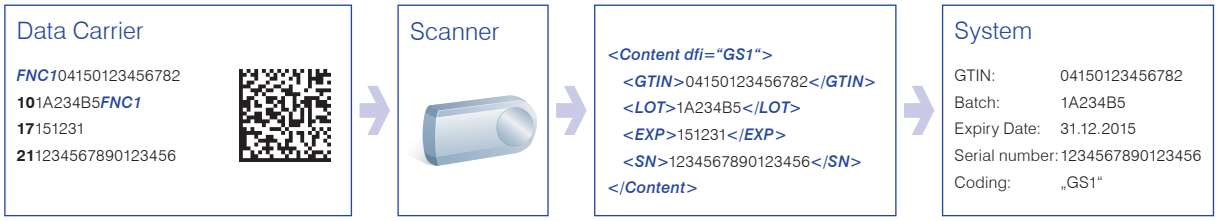
Example 3: Data transfer from scanner – ASC-Format

Product Code: PPN | Data Identifier: DI | Data Format Identifier: IFA



Example 4: Data transfer from scanner – GS1-Format

Product Code: GTIN[1] | Data Identifier: AI | Data Format Identifier: GS1



If you have any questions or suggestions about this appendix, please do not hesitate to contact securPharm.

1 At this technical level there is no difference between a NTIN and a GTIN. Hence the comprehensive term GTIN is used.

Appendix D
Details for quality inspection of the Data Matrix Code

D.1 General

The quality inspection is composed of the components of code scanning (***D.2***) and measurement of print quality (***D.3***). The marketing authorisation holder determines depending on his processes whether the code scanning check is performed according to ***D.2.1*** or ***D.2.2***.

Based on the code scanning check, it must be ensured that each package bears a code with the correct content. Packages without a code or with incorrect content will be removed. Based on this check, the serial number is valid and can be entered into the ACS-MAH-System together with the other necessary data.

Scanning systems vary strongly in their performance. Manual scanners are typically very error-tolerant while inline high-speed scanners are more demanding in terms of print quality. Therefore, identical print qualities can result in different initial scan rates with different scanning systems.

D.2 Code scanning check

The Code scanning check tests if

- the code is present;
- the correct symbology was used; and
- the content complies with the specifications.

A check of the human readable text print with the code content is also part of a code scanning check, since this clear text information counts among the required components of the unique identifier. In digital printing, every single package must be checked (100 % scanning).

During the packaging process, it must be ensured that any packages without unreadable codes or carrying codes with contents deviating from the requirements are rejected.

The code scanning check does not include a measurement of print quality: To assess print quality, a measurement as demanded in Article 6 of the Delegated Regulation is obligatory.

Typically, print quality is determined with a sample spot check measuring device (see ***Appendix D.3***).

D.2.1 Manual code scanning check

For pharmaceuticals that are produced in small quantities the scan code scanning check can be performed with a manually operated scanner and the data can be transmitted to the database. In this case, the clear text data can be checked either purely manually or with the help of a manual scanner.

D.2.2 Inline code scanning inspection

Inline code scanning inspections are built-in, fully automated camera based inspection systems which perform the code scanning scan check described previously in Annex ***D.2***. The inline scanners have been optimized for logistic processes to a high reading rate and error tolerance based on the corresponding software algorithms and optoelectronic and mechanical properties.

The inline inspection can be a pure code scanning check or, in addition, pseudo grading can be performed. Pseudo grading is the expanded capability of scanning systems to analyse and determine print quality in the style of the ISO/IEC 15415 measuring method.

However, it must be noted that the assessment of contrast and dimensional measurement values in the style of ISO/IEC 15415 measuring method does not constitute a measurement. Nonetheless, these results can be used to assess qualitative parameters for the purpose of recognizing fluctuations in print quality. This offers the advantage that the code scanning check of all packs is associated with a stability check of print quality.

A metrological assessment pursuant to ISO/IEC 15415 (***D.3***) based on inline inspection currently fails due to the conditions of the available systems. The settings for efficient code scanning in terms of exposure, sharpness, geometry as well as available different ambient light and the later adjustment of camera and light positions lead to print quality assessment results that deviate more or less strongly from a genuine measurement (***D.3***). These partly unsystematic deviations cannot be adjusted and may lead to seemingly random different results.

To take this fact into account, additional random sample measurements are typically conducted in parallel to the

inline inspection (see ***D.3***). Sampling volume and frequency depend on the stability of the printing process and the pseudo grading.

If a device for inline inspection cannot meet the metrological requirements in terms of calibration and adjustment as well as traceability of the results to national standards, sample taking measurements will be indispensable. Only then will the requirements of the Delegated Regulation be met.

D.3 Measurement in accordance with ISO/IEC 15415

In Article 6 the Delegated Regulation demands an assessment of print quality.

Usually, this process employs measuring devices whose construction is stipulated by ISO/IEC 15415. These are optical measuring devices with a predefined measuring precision (ISO/IEC 15426-2) and whose results can be traced back to national standards (e.g. PTB, NIST).

Apart from the information mentioned in ***Chapter 7*** regarding the parameters of the measuring devices, their alignment and calibration (DIN 1319-1) must absolutely be observed.

D.4 Measuring conditions according to ISO/IEC 15415

The code to be measured is described in ***Chapter 6.1*** and the print quality inspection is described in ***Chapter 7***.

The testing parameters (***D.5***) are meaningful and comparable only if they are determined under predefined conditions. The international Standard ISO/IEC 15415 shows various possibilities and demands that the user specification stipulate these measurement conditions.

The corresponding requirements for measurement conditions are as follows:

Property	Stipulation
Type of light	Red light, wavelength of 660 nm (+/-10 nm)
Filtering (synthetic aperture)	80 % of the matrix cell size (module size) of the code to be measured
Illumination angle	4 lights that illuminate the field of view from four sides below 45°
Camera angle *)	90° above the code (perpendicular to the plane of packaging)
Distance *)	Must cover illumination angles, image must be in focus and resolution must be sufficient.
Resolution *)	At least 10 x 10 camera pixels per matrix cell or less, if it can be proven that the required measuring precision of ISO/IEC 15426-2 is met. Based on past experience, less than 5 x 5 camera pixels lead to unusable results.

*) typically specified by the construction of the measuring device

D.5 Parameters for print quality

The Delegated Regulation stipulates the minimum required parameters for assessing print quality. For a better overview, the following table presents the terms from the Delegated Regulation and the corresponding standards in German and English and the terminology from the standards is listed completely.

Table 3: Testing parameters for the assessment of print quality:

Article 6 para. 1 of the Delegated Regulation		Standard ISO/IEC 15415		Technical meaning
English version	German version	English	German[1]	
(a) the contrast between the light and dark parts	(a) Kontrast zwischen hellen und dunklen Elementen	SC = Symbol contrast	Symbol-kontrast	Contrast is determined between the brightest and the darkest spot in the overall symbol. To achieve this, the brightest and darkest matrix cells are determined respectively (including fixed patterns). The difference between these reflection values is the symbol contrast. Decreasing values result in the devaluation of this parameter.
(b) the uniformity of the reflectance of the light and dark parts	(b) Homogenität der Reflexion heller und dunkler Elemente	Modulation, reflectance margin and contrast uniformity	Modulation, Reflexions-bereich und Kontrast-gleichmäßig-keit	Ideally, all white areas should have the same reflection values, as should the black ones. Based on material transparency, print gains, grid distortions and uneven print blackness as well as uneven brightness of the substrate, the unevenness of the reflection value will increase. This results in the devaluation of this parameter.
(c) the axial non-uniformity	(c) axiale Inhomogenität	AN = Axial nonuniformity	Axiale Ungleich-mäßigkeit	The axial distortion assesses whether a symbol was printed stunted or stretched in its entirety. The larger the distortion, the worse the assessment of this parameter.
(d) the grid non-uniformity	(d) Inhomogenität des Rasters	GN = Grid nonuniformity	Gitterungleich-mäßigkeit	The grid non-uniformity looks at the code matrix in detail. Deviations of individual matrix cells from ideal checkerboard geometry result in devaluation of this parameter.
(e) the unused error correction	(e) nicht genutzte Fehlerkorrektur	UEC = Unused error correction	Ungenutzte Fehlerkorrektur	Individual white or black matrix cells that have the wrong colour based on flawed spots or stains are recognised by the error correction and the data are reconstructed from the redundant matrix cells. UEC is devaluated in accordance with the unused error correction.
(f) the fixed pattern damage	(f) Beschädi-gung des festen Musters	FPD = Fixed pattern damage	Beschädigung der festen Muster	The Data Matrix Code contains areas that serve the purpose of orientation and grid reconstruction. These areas do not contain any data. Damage of these patterns results in devaluation of this parameter.
(g) the capacity of the reference decode algorithm to decode the Data Matrix.	(g) Kapazität des Referenzdekodie-rungsalgorithmus zur Dekodierung der Datenmatrix	Decode	Dekodierung	Decoding and grid reconstruction in a code measurement is done with the standardised reference decode algorithm. If decoding fails, this results in devaluation of this parameter.
—	—	Contrast uniformity	Kontrast-gleichmäßig-keit	MOD[2] values are determined for all code words. The MOD values are used for determination of the modulation and the reflectance margin. Contrast uniformity is the worst individual MOD value (informative, relevant for calibration according to ISO/IEC 15426-2).
—	—	Print gain	Druckzuwachs	Informative parameter that indicates whether a symbol is overprinted (too bold) or underprinted (too thin).
—	—	Module size	Modulgröße	The size of a matrix cell of the overall code is known as module size. The scanner properties in terms of scanner depth of field, scanner resolution and minimum scanning distance depend on the module size.
—	—	Matrix size	Matrixgröße	The entire code consists of individual matrix cells (= modules) of a certain, identical module size. Standard ISO/IEC 16022 defines 10x10 modules as the smallest matrix size and 144x144 as the maximum matrix size. In practical applications, the area of permitted matrix sizes is limited in order to restrict the proportion of camera resolution to the matrix size and in order to have a sufficiently large number of camera pixels per module available. This is required for scanning reliability.

The final assessment is determined by the testing parameter with the worst measuring result. The quality levels are represented in a table in *Chapter 7*.

1 The German terms were created by the authors, since no German version of this standard exists.

2 MOD is the assessment of the modulation for a single code word of the Data Matrix Code. A code word is a small part of the code, which always consists of 8 matrix cells.

Appendix E
Glossary

As a matter of principle, the terms and definitions of ISO/IEC 19762 apply.

The following are additional terms and abbreviations used in this document:

ACS PharmaProtect GmbH (ACS): The operating company of the database system of the pharmaceutical industry (www.pharmaprotect.de) at securPharm.

AMG: In the interest of proper pharmaceutical care for humans and animals, it is the purpose of the German Medicinal Products Act (AMG) to guarantee safety during the circulation of medicinal products, specifically ensuring the quality, efficacy and safety of medicinal products in accordance with the provisions contained in the AMG (see section 1 AMG).

Application Identifier (AI): Identifier specified by the users of GS1, which exactly defines the encoded data content. These are valid worldwide and applicable in multiple sectors in accordance with ISO 15418. Published by GS1 in the German-speaking region under the term "Datenbezeichner".

Article Number: The number that clearly identifies an article or product. A synonym for article number is product number. In this document, the term "article number" is used when referring to article identification in the retail sector. This terms stands in contrast to the product code, which represents part of the UI in terms of the Delegated Regulation. As a result, both an article number and a product code can be assigned to a product.

ASC-Format: Is structure that uses format 6 of ISO/IEC 15434 and the ASC MH10 Data Identifiers (DI) of ISO/IEC 15418 (reference to ANSI MH10.8.2). The specifications of IFA Coding Systems are based on that format (see also data identifier)

Barcode: Optical data carrier consisting of lines. Colloquially, two-dimensional matrix codes are sometimes referred to as 2D barcodes. This also includes the Data Matrix Code.

Blue Box: For centrally registered medicines in Europe, the leaflet has to be compliant to article 57 of the EU Directive 2011/83/EC. Country specific requirements have to be printed inside the so called "blue box" (visually distinguished by a blue colored frame). These are specified by the EMA respectively the CMDh in the "blue-box-requirements".

EMA:
- Notice to Applicants
- http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm
- Volume 2C Regulatory, „Guideline on the packaging information of medicinal products for human use authorised by the Union"; ANNEX: ‚Blue box'.

CMDh:
- http://www.hma.eu
- Procedural Guidance
- Application for Marketing Authorisation (MA), „Blue-box requirements".

CMDh: The Co-ordinated Group for Mutual Recognition and Decentralised Procedures – Human is set -up in accordance with Directive 2001/83/EC for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States, in accordance with the Mutual Recognition Procedure (MRP) or the Decentralised Procedure (DCP).

Clinic Component: A clinic component is a package that resembles the retail pack but cannot be sold individually. A PZN is assigned to the clinic component for package identification that refers to the contents and the characteristic of "clinic component". Bundled clinic components make up clinic packs to which a retail-relevant PZN is assigned.

Code 39: A barcode type specified in ISO/IEC 16388. The printed space requirement of this code is high for a relatively low data volume. The Code 39 is used as a data carrier for the PZN until further notice.

Continuous Ink Jet (CIJ): This is a form of ink jet printing. Usually, this printing process generates dot codes, which are explained in the glossary. The printing process creates a constant stream of ink droplets, which is deflec-

ted electrostatically. Due to the high solvent content, the ink dries and adheres very well to all non-porous surfaces. The resolution is low.

Data Identifier (DI): Data identifiers assigned by the ASC MH10 Data Identifier Maintenance Committee that are listed in the international standard ANSI MH10.8.2. The data identifier always ends in an alphabetic character, which can be preceded by a two- or three-digit number to distinguish between different versions.

Data Matrix: In the German version of the Delegated Regulation, the Data Matrix Code is translated as "Datenmatrix". See Data Matrix Code.

Data Matrix Code: A two-dimensional matrix code consisting of square elements. In the ECC200 version pursuant to ISO/IEC 16022, the code includes error correction in accordance with the Reed Solomon code for missing dots or damaged spots. The same-coloured, neighbouring elements of the code should directly transition to each other without interruption. (In the German version of Delegated Regulation 2016/161, the Data Matrix Code is translated as "data matrix" ("Datenmatrix").)

Delegated Regulation: The Delegated Regulation (EU) 2016/161 of the Commission of 2 October 2015, supplements Directive 2001/83/EU of the European Parliament and the Council by stipulating exact provisions regarding the safety features on the packaging of medicinal products for human use.

DFI – Data Format Identifier: Defines the parameters according to the ISO standard. Additionally, it sets out the guidelines for the use and form of the following parts: the envelope data according to ISO/IEC 15434, the specific application identifier (AI or DI), whether a macro should be used (ISO/IEC 16022) and the appropriate syntax. Currently, "IFA" and "GS1" are defined as the value for the DFI.

Dot Data Matrix Code: This is a data matrix code consisting individual, round dots. The data matrix standard does not specify a dot code variant. In practice, there are many dot code data matrix applications. They require scanners capable of reading such applications. This application is an open system that does without the data matrix dot code variant.

Dotcode: This is a separate code type consisting of individual, detached dots. This code type is mentioned here in order to ensure a clear distinction between the dot code and a data matrix code in the dot variant.

European Medicines Agency (EMA): European regulatory agency for certain pharmaceuticals. Grants approval for medicinal products with centralised marketing authorisation in Europe.

European Medicines Verification Organisation (EMVO): This non-profit organisation established by the European stakeholder associations operates the European hub (HUB) and connects the national medicines verification systems (NMVS) to the EMVS.

European Medicines Verification System (EMVS): The system landscape consisting of the European hub (HUB) and the connected national medicines verification systems (NMVS).

Falsified Medicines Directive (FMD): The European Directive 2011/62/EU amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Global Trade Item Number (GTIN): A globally unambiguous article number used in many sectors (FMCG, chemistry, healthcare, fashion, DIY, military, banking, etc.). The GTIN (formerly EAN) can be encoded in various data carriers, e.g. in a barcode of the EAN-13 type. Other coding versions of the GTIN in GS1- 128, the Data Matrix Code and GS1-DataBar are possible. The IA in charge is GS1.

GS1 – registered trademark: GS1 is the abbreviation for Global Standards One, which is registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2 and manages the global GS1 number systems.

HIBC – Health Industry Bar Code: The HIBC is a compressed structure and primarily used for labelling medicinal products. The HIBC is prefixed by the system identifier "+", followed by alphanumeric product codes of 2 to 18 digits, followed by the variable product data (see www.hibc.de). HIBC is another issuing agency (IA) registered in accordance with ISO/IEC 1549-2 that also provides for the use of the data identifier (DI).

Identifier: To indicate the content of a data element these

are headed by standardised identifiers. The most common identifiers are the ASC MH10 Data Identifiers (DI) and the GS1 Application Identifiers (AI). In ANSI MH10.8.2 both kinds are included separately as well as being mapped to each other. Whenever Data Identifiers and Application Identifiers are meant, this document uses the short term identifier.

IFA: *IFA Informationsstelle für Arzneispezialitäten GmbH* (www.ifaffm.de). The organisation assigning the PZN and the PRA code for use of the PPN. The IFA is also registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2.

Issuing Agency (IA): An organisation in charge of assigning number systems that is accredited in accordance with ISO/IEC 15459-2. An issuing agency is able to provide its system participants with a system for the unambiguous identification of objects on a worldwide scale. The ISO has commissioned industry association AIM to serve as registration authority.

Issuing Agency Code (IAC): The registration code assigned to an issuing agency (IA) by the Registration Authority for ISO/IEC 15459.

Marketing Authorisation Holder (MAH): Pursuant to Section 4 para. 18 of the German Medicinal Products Act (AMG), the marketing authorisation holder owns the marketing authorisation or registration for pharmaceuticals subject to approval and registration as well as the party circulating a medicinal product. Both the marketing authorisation holder and the co-distributor are pharmaceutical entrepreneurs, but the latter does not hold the marketing authorisation. As so-called suppliers, both the marketing authorisation holder and the co-distributor can apply for a PZN for their medicinal products with the IFA. Typically, however, only one of the two applies for the PZN and becomes the registered supplier with the IFA. This supplier will also be the contractual partner of ACS and responsible for uploading the data of his PZN.

Module Size: Specifies the ideal size of a matrix cell in the Data Matrix Code.

National Trade Item Number (NTIN): A globally unique item number in which national article numbers are embedded and a GS1 prefix is used. For the PZN, the prefix "4150" has been assigned. As for GTIN, "01" must be used as application identifier (AI). Analogously, the data identifier "8P" must be applied when using the ASC format.

National Medicines Verification Organisation (NMVO): A non-profit organisation for operating the national medicines verification system (NMVS). In Germany, this is securPharm e. V.

National Medicines Verification System (NMVS): The national medicines verification system for a member state.

OTC Medicines: OTC (= over the counter) is a term used for non-prescription drugs. Pursuant to Section 48 of the German Medicinal Products Act (AMG), medicines are classified as non-prescription, if they do not endanger the user's health when used as intended, even if they are used without medical supervision. Non-prescription drugs are further categorised into pharmacy-only and freely sold medicines.

Pharmacy Product Number (PPN): A globally unique article number for health care products into which national article numbers are embedded. For embedding the German PZN the product registration agency code "11" is used as a prefix, followed by the national article number (in Germany the PZN), followed by a two number check digit. The data identifier for a PPN is "9N".

Pharmazentralnummer (PZN): National article number of German pharmaceutical products or merchandise typically sold in pharmacies. Since 2013, the PZN has had eight digits. Assignment of the PZN is governed by law and is the responsibility of the IFA. The retail sector uses the PZN for unambiguous item identification while the health care sector uses it for billing purposes. See also http://www.ifaffm.de/service/index.html. The corresponding number in Austria is also known as PZN. However, it originates from a different circle of numbers and is managed by the corresponding Austrian issuing agency.

PPN Code: Describes a Data Matrix Code ECC200 in accordance with ISO/IEC 16022 and the data structure and syntax of ISO/IEC 15418/ANSI MH10.8.2 and ISO/IEC 15434. As the leading data element, the PPN Code includes the Pharmacy Product Number (PPN) and other data elements depending on the application in question. For pharmaceuticals subject to mandatory verification, these are always the serial number, batch number and expiry date.

Product Code: Pursuant to the Delegated Regulation, this is the safety feature on which the verification is based in connection with the serial number. The combination of product code and serial number is globally unique for each pharmaceutical package. In Germany, the product code used for a verification pursuant to the FMD is the PPN. In the data matrix code the product code can be included in the format of a PPN or NTIN, which both contain the PZN.

Product Registration Agency Code (PRA Code): Two-digit prefix to the unique identifier of a PPN. Assigned and managed by the IFA.

Product Registration Agency (PRA): Issuing agency of (national) article numbers that are transferred into the PPN together with the PRA Code.

Pseudo Grading: The term pseudo grading describes an assessment of print quality modelled after the ISO/IEC 15415 standard. This method is used by camera systems that are firmly integrated into a production line, perform scan check and assess print quality criteria. Since these camera systems are not standardised measuring devices, the term is prefixed by the word “pseudo”.

Randomised Serial Number: A serial number generated at random based on a deterministic or non-deterministic randomisation algorithm.

Rx Drugs: Prescription drugs are often colloquially referred to as Rx drugs.

securPharm: An initiative to protect patients from falsified medicines in the legal supply chain in Germany. It is sponsored by a consortium of pharmaceutical, wholesalers’ and pharmacists’ associations. securPharm e.V. is the non-profit organisation operating the national medicines verification system in Germany.

Unique Identifier: Pursuant to Article 3 of Delegated Regulation 2016/161, this term describes the safety feature that facilitates the verification and identification of an individual pharmaceutical package.

Verification: Describes the process of detecting falsifications or duplicates with the help of a serial number printed on pharmaceutical packages. In the field of optical codes, the term verification is also used for the quality inspection of printed codes. For the sake of unambiguous terminology, this specification only uses the term “verification” within the context of detecting falsifications. Print quality inspection is always described as barcode or matrix code verification.

XML: This abbreviation was derived from the term “Extensible Markup Language”. XML is a markup language to represent hierarchically structured data in the form of text data.

Appendix F
Bibliography

F.1 Standards

ISO 22742: Packaging - Linear bar code and two-dimensional symbols for product packaging

ANSI MH10.8.2: Data Identifier and Application Identifier Standard

DIN 16587: Information technology – Automatic identification and data capture techniques – Data Matrix Rectangular Extension DIN 16587 Informationstechnik – Automatische Identifikation und Datenerfassungsverfahren – Rechteckige Erweiterung des Data Matrix-Codes

ISO/IEC 15418: Information technology – Automatic identification and data capture techniques – GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance; references to ANSI MH10.8.2

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

ISO/IEC 15434: Information technology – Automatic identification and data capture techniques – Syntax for high-capacity ADC media

ISO/IEC 15459-2: Information technology – Unique identifiers – Part 2: Registration procedures

ISO/IEC 15459-3: Information technology – Unique identifiers – Part 3: Common rules for unique identifiers

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

ISO/IEC 19762: Information technology – Automatic identification and data capture (AIDC) techniques – Harmonised vocabulary

ISO 2859-1: Sampling procedures for inspection by attributes Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

ISO 3951: Sampling procedures and charts for inspection by variables for per cent nonconforming

F.2 Reference to specifications:

The specifications listed below contain the necessary details of coding, specifically to the two possible structures in the Data Matrix Code:

A Specifications of the IFA:

See "IFA-Coding System: PPN-Code Specification for Retail Packaging": http://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html

Part of the IFA coding system, see: http://www.ifaffm.de/en/ifa-codingsystem.html

B Specifications of GS1:

1.) Identification of Medicines in Germany – NTIN Guideline for use in the securPharm pilot project (https://www.gs1-germany.de/fileadmin/gs1/basis_informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf).

2.) Labelling of pharmaceuticals in Germany – NTIN guide for use in the securPharm pilot project (https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/).

3.) General GS1 Specification (www.gs1.org).

Appendix G
Document Maintenance Summary

Version	Date	Type of change	Change
V 1.0	2012-06-13	First release	
V 1.01	2012-08-20	Layout/content correction	Chapters: 4; 5.1; Appendices: A; C; H; I (update)
V 1.02	2012-11-05	Layout/content correction	Editorial changes
V 1.03	2013-12-03	Layout/content correction	Chapters 4.2;6; Appendix H
V 2.00	2016-03-15	Layout/content correction	Incorporated requirements from the Delegated Regulation (EU) 2016/161 into the corresponding chapters
V 2.01	2016-05-10	Content added/removed	Chapters 4.5, 5.2.5, 6.4, 6.6 and appendix E
V 2.02	2016-07-01	Layout/wording correction	Title, chapters 2, 6.2, appendix F
V 2.03	2017-05-05	Content added/removed	Chapters 4.5, 4.6 and 5.3

securPharm

Imprint

securPharm e.V.
Hamburger Allee 26–28
60486 Frankfurt am Main
Germany

Internet: http://www.securPharm.de

The content was created with the greatest care. If you discover errors or omissions, please contact us. This document is a translation of the German version 2.03 of the securPharm coding rules and for your convenience. If there are any deviations to the German version – the German version applies.

Note regarding the preparation of this specification:

The Working Group (AG) “Coding” of the securPharm project created this specification. It consists of the following members (in alphabetical name order):

- **Dr. Ehrhard Anhalt,** Bundesverband der Arzneimittel-Hersteller e.V. (BAH), Bonn
- **Martin Bergen,** securPharm e.V., Frankfurt/Main
- **Michael Borchert,** Avoxa – Mediengruppe Deutscher Apotheker GmbH, Eschborn
- **Thomas Brückner,** Bundesverband der Pharmazeutischen Industrie e.V. (BPI), Berlin
- **Michael Dammann,** PHAGRO | Bundesverband des Pharmazeutischen Großhandels e.V., Berlin
- **Paul Rupp,** (Leiter der AG) IFA Informationsstelle für Arzneispezialitäten GmbH, Frankfurt/Main
- **Dr. Wolfgang Stock,** ACS PharmaProtect GmbH, Berlin
- **Wilfried Weigelt,** Mitglied im Normenausschuss DIN NA 043-01-31 AA