

QUICK GUIDE

for globally unique labeling of items
by ISO/IEC 15459 Company ID Numbers (CIN)



with excerpts of the
AIDC Standards Report
and informative appendixes.

Quick Guide for globally unique labeling of items

ISO/IEC 15459 - Hierarchical A, B, C, D structure

The standard "ISO/IEC 15459 Unique Identification" supplies the rules for generation of of globally unique codes. Figure 1 is showing the hierarchical structure from A to D and syntax level (E). ISO/IEC adopted the original concept of the hierarchy from CEN EN 1572 and extended it from its validity for transport units to all kinds of physical and virtual items. The rules for unique codes are as simple as effective: ISO accredits a "Registration Authority" (A), which in turn registers Issuing Agencies (B), which assign unique "Company Identification Codes" to companies and institutions (C) on request. Companies that have got a "CIN" are in a position to label everything that shall be identified uniquely and everywhere. This includes not only products, packaging, containers, transport units, but also locations, papers, facilities, even persons or their ID cards or wristbands. Identifiers tell the computer what it is about, the IAC with the CIN where the code issuer was.

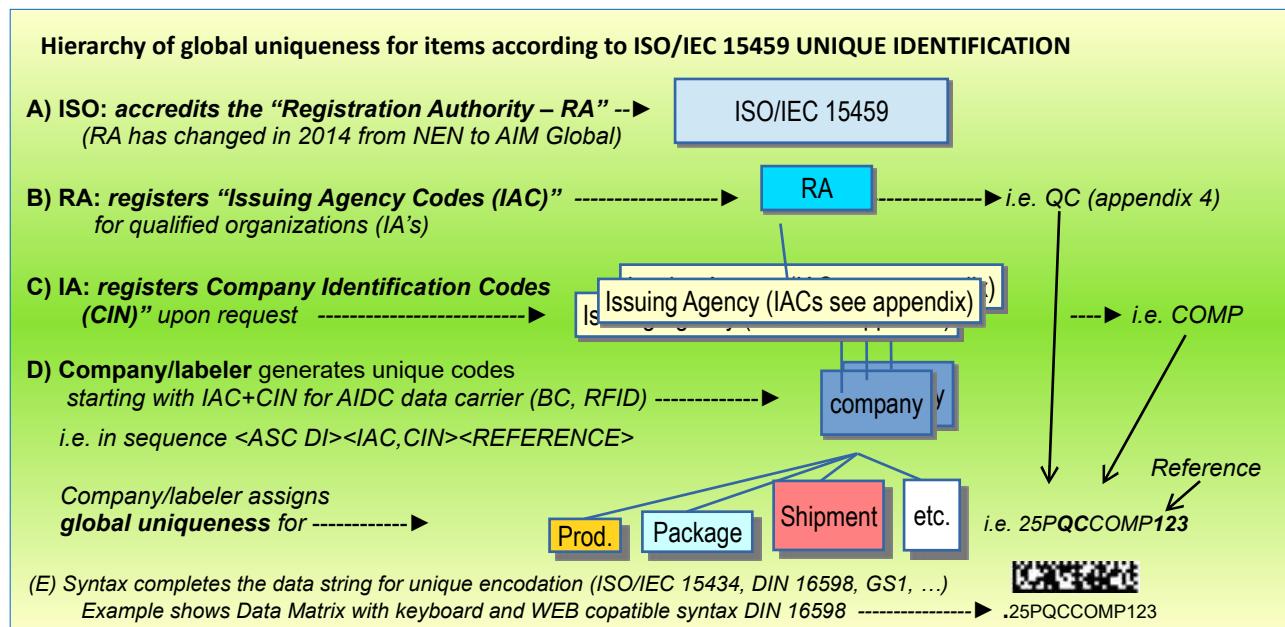


Fig. 1) Hierarchically distributed responsibility for unmistakable unique labelling

How do you generate a unique product code?

The prerequisite for generating an unique code is the receipt of a CIN from an issuing agency. This issuing agency also determines the syntax of the relevant code. If the issuing agency supports the "ISO/IEC 15418-ASC MH 10 Data Identifier (DI)s)", then the product reference can be alphanumeric. In case of GS1 syntax with Application Identifiers (AIs) the then it is numeric. The data length for ASC DI data elements can be from 1 to over 20 characters. For GS1 AIs, the product reference like the "Global Trade Item Number (GTIN)" is 14 digit long including company/location code and product article number. The Issuing Agency EHIBCC supports ASC DIs as well by the HIBC structure with up to 18-digit alphanumeric product codes. The "Quick Guide" below has 5 steps.

Quick Guide with 6 steps to get uniqueness

for a unique product code, e.g. for the product reference REF: **M4215R73**:

- I) Determine the format of the product reference with fix or variable length, e.g. for **M4215R73**
- II) Decide on an Issuing Agency with its format specifications for product codes
 - a) if there are 5 digits, → both ISO/IEC 15418 ASC Data Identifiers and
GS1 Application Identifiers and HIBC syntax can be used (also depending on the customer group).
 - b) if more than 5 digits or alpha characters → go to a registry that supports ASC DIs.
- III) Apply for a CIN, here for direct coding of **M4215R73** e.g. "COMP" from "E.D.C.". (IAC "QC") with support of ASC DIs for alphanumeric product codes.
- IV) Choose the appropriate ASC-DI for the sequence "unique product code" <DI><IAC><CIN><REF> and form the data string: ASC DI "25P"
→ a) generate the data string for REF M4215R73: <25P><QC><COMP><**M4215R73**>
→ b) in case of individual serialization add DI "S" and serial number e.g. 1234567 for complete coding:
25PQCCOMP**M4215R73**[^]S1234567 (Additional data element, such as LOT, date, etc. as required)
- V) Select syntax ISO/IEC 15434 (for high volume data) or DIN 16598 (standard)
- VI) Choose the appropriate medium, e.g. Code 128 for a) or Data Matrix and/or RFID for b)



Fig. 2) Serialized product code from "COMP" with REF. M4215R73 in Data Matrix and RFID and KB compatible ASC syntax

ASC Data Identifier Maintenance Committee (DIMC)



ASC Data Identifiers are maintained by the Material Handling Institute (MHI) accredited by ISO/IEC 15418.

MHI was created 1945 to deliver solutions to common industrial challenges for manufacturers in the material handling industry. Patrick Davison, Director, Standards, is proud to announce the 75 years celebration, a remarkable milestone in its history. Right now MHI has got many responsibilities, one is the maintenance of ASC Data Identifiers standardized by ISO/IEC 15418, part ANS MH 10.8.2. Meanwhile ASC Data Identifiers are used globally in rather all business areas. The structure with alphanumeric product codes of variable length gets more and more friends even after a more than 30 years evidence. The responsibility for maintenance of ANS MH 10.8.2 has been assigned to MHI. Under this umbrella the Data Identifier Maintenance Committee (DIMC) has been established for the daily work. The DIMC members are international experts from many countries and business areas working together to achieve global functionality of the ASC Data Identifiers (ASC DI's) for AIDC applications worldwide.

In July 2020 Mr. Bill Hoffman has been confirmed as acting chairman. Requests for assignment of new ASC Data Identifiers get on his desk for processing it with his group of experts as just happened with a request from the health care area (see chapter <New ASC DI "54P">.

ASC DIs are used to identify anything even spare parts as seen at the actual example with not concatenated single data elements of the AIDC supplier Zebra Technologies (Fig. 3).



Fig. 3) Old school spare part label applied with single data elements each in one CODE 39

The sample Fig. 3) shows how long the "old school" style of labels is resisting while other companies have been using 2D symbols for a long time already. Nevertheless, it still works.

URL for Publicly Available Continuous Maintenance version of ASC MH10.8.2 Data Identifiers and Application Identifiers:
<http://www.mhi.org/standards/di>

ASC DI user question: "Shall a ASC DI stand alone without data?"

This question has not been passed to DIMC yet but it popped up already at the ADC working group of EDIFICE.

In fact, it happens that sometimes No Data are printed after an ASC DI. This would lead to different assumptions.

The sample ISO/IEC 15434 data string below encoded in a Data Matrix symbol shall illustrate such case where ASC DIs are present but some of the data are absent: -----?



]>^R_S 06^G_S JQCELMIXLP345^G_S 2LCZ14800^G_S 1PROD77^G_S S76345296^G_S S^G_S S^G_S S^R_S E_{O_T}

The sample shows a Licence Plate, a location code, a product code, one serial number headed by "S" and three "S" following indicating a serial number but don't show a data value.

If data are missing, e.g. after ASC DI „S“ it might be recognized as

- a) the value might be forgotten
- b) the DI may have been placed by mistake
- c) an absent value might mean there is a part but no serial number
- d) it is about an in-house solution not meant for the open supply chain

The sample of a data string with concatenated data elements has been chosen because it is unlikely that a single data element would not have data, like an indicated License Plate without a number below:



Conclusion: ASC Data Identifiers define and identify a specific data field. This is true for complete data elements applied with ASC DI and data. For open systems Printing ASC DIs without following data values shall be avoided because valid data elements can be processed at the point of scanning only where the definitions of the ASC DIs are implemented. Probably EDIFICE will recommend to DIMC discussions on a clarification in ANS MH 10.8.2 on this issue.

New ASC DI “54P” for optimization of logistics within the Global UDI project



After registration of ASC DI “53P – Identifier for Specific Marine Equipment approved under the European Union Directive on Marine Equipment (2014/90/EU and Implementing Regulation (EU) 2018/608” a new ASC DI has been requested by the coordinating association in health care “FIDE” for optimizing logistical processes in conjunction with the

Global UDI project.

It is about an ASC DI not directly for product labelling of **Medical Devices (MD)**, but for use in ADC containers like ISO/IEC 15434. The new ASC DI shall point directly to the UDI-DI data field of **public UDI data bases** built up by the responsible health care departments of countries and regions like

the GUDID in the US and EUDAMED for Europe, etc. MD manufacturers have to register their products jointly with the product **master data in such public UDI data bases**. The product ID stored in the data base is called “UDI-DI” (Unique Device Identification – Device Identifier). On product level the UDI-DIs are encoded in a barcode format of one of the four UDI accredited Issuing Agencies (GS1, HIBCC, ICCBBA and IFA for Europe). The idea of the new ASC DI is to include the data format as stored in the UDI data base in a uniform way. In consequence, same UDI-DI as carried by a GS1, HIBCC, ICCBBA ISBT 128 or in an IFA barcode on the product can be carried in one ADC container and the UDI-DIs can be embedded equally flagged with same ASC DI. After discussion and polishing the request by the DIMC, the ASC DI for UDI-DIs has been assigned and published with ANS MH 10.8.2 on 2020-08-27 as follows:

“54P – Identifier for UDI-DI (Unique Device Identification - Device Identifier) for Medical Devices (MD) and In-vitro-Diagnostics (IVD) as the unique key to public UDI data bases (GUDID, EUDAMED, etc.)”.

The wording explains it clearly: The data element is referring directly to the specific field in the UDI data base.

Fig. 4) is illustrating the role of the ASC DI “54P” to harmonize UDI-DI data elements with the formats in the data bases.

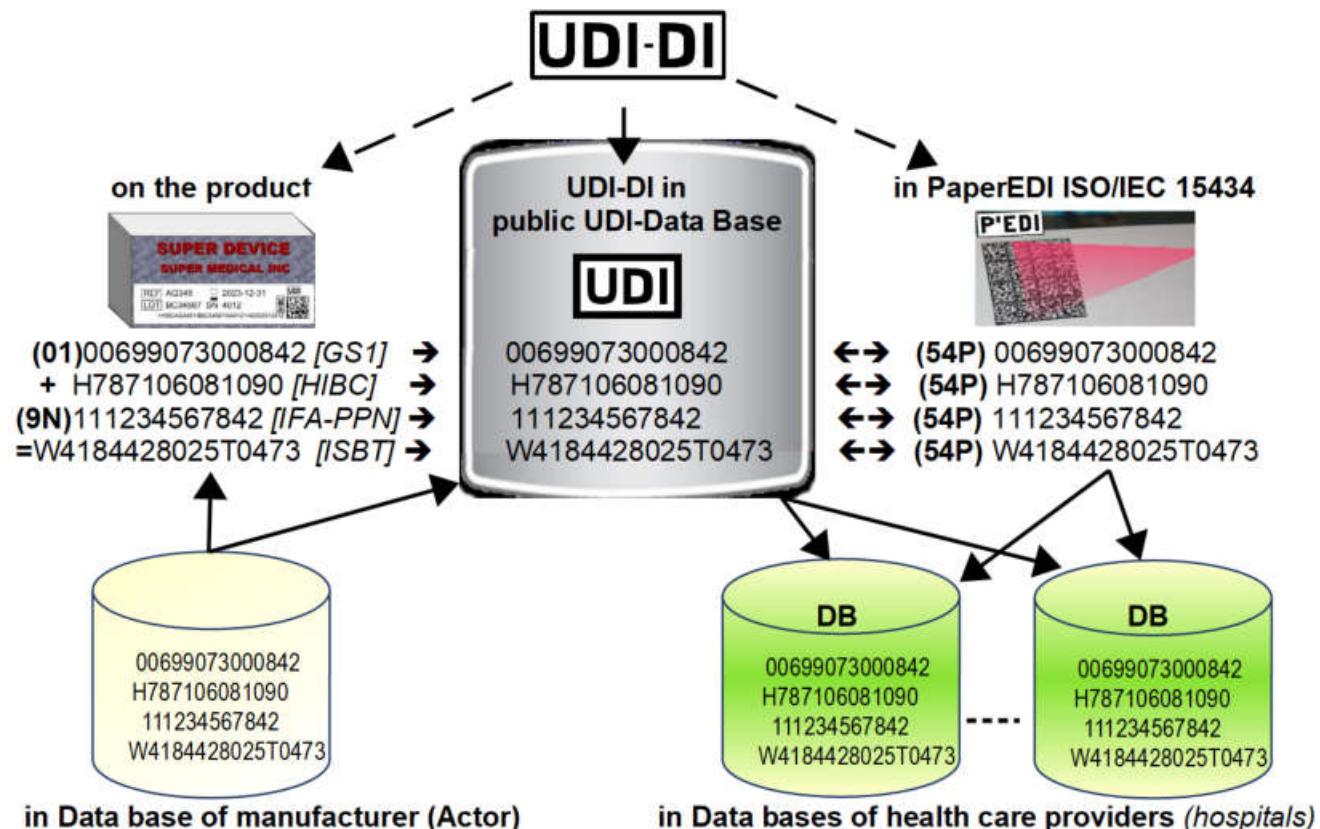


Fig. 4) ASC DI “54P” harmonizing UDI-DIs for ADC envelope (P’EDI) and direct access to public master data

“54P for PaperEDI encoded in an ADC container according to ISO/IEC 15434

The targeted application for the ASC DI “54P” is the so called “PaperEDI” solution to carry shipment contents in one 2D-symbol on ISO 15394 shipment labels or printed on delivery notes. One scan is enough to catch all of the listed products and related date. If the product code is headed by ASC DI “54” the product master data can be accessed at the UDI-Data base and downloaded automatically.

Fig. 5) Shipment note applied with Data Matrix as P'EDI code carrying all product data of the shipment →



ASC DI “9N” IFA Coding System for UDI in Europe



The IFA Coding System originally was developed for medicinal products but used for Medical Devices (MD) and In-vitro-Diagnostica (IvD) as well. In conjunction with enforcement of the Regulations for MDs and IvDs the IFA GmbH, maintaining the IFA Coding System has been accredited for the UDI-System in Europe. The IFA Coding System is strictly using ASC Data Identifiers embedded in the ASC container ISO/IEC 15434. The registered ASC DI for the coding system is “9N” used for a single product’s label. As UDI-DI existing references can be used like practiced with the HIBC code but also pre-registered national codes. As ASC DIs for the variable product data in the “PI segment” of an UDI product the standard ASC DIs are used like “1T” for LOT, “S” for SN, etc. Fig. 6) below shows a typical UDI label applied with Data Matrix in IFA Coding

System structure.

Fig. 6) MD label applied with UDI
in IFA Coding System structure, source https://www.ifaffm.de/en/ifa-codingsystem/udi/udiIssuing_entity.html

ASC DI “5R” as a “Digital Logo”

QR is used increasingly for company specific applications and the labelers tend to brand their QR to show who is the originator, not taking care for the encoded data. Since “5R” has been born, originators are recognizing that they can brand the code not only graphically with their logo but also they can put their brand mark in front of their data stream. The sample below shows the logo of EDC graphically and digitally by aid of ASC DI “5R”.

Fig. 7) Logo optically visible on the code and digital logo in the code “.5RQCDATA:.....” →



Note: Labeler printing logos in a QR should go for the next higher Error Correction Level to compensate the damages of data pattern, nevertheless finder pattern and clock tracks should not be covered by any graphic.

ASC DI „34L“ for P2P INTERNET of THINGS access (DIN SPEC 16589)

Quick Link to IoT via “Pointer to Process -P2P”

Internet access with smartphone via QR code is common practice today, but there are even more developments featuring Internet access by regular barcode (or RFID).

This is a rising demand: Using IoT for access to item information by scanning a regular item code applied for item identification and tracking & tracing purposes. A regular URL in a QR Code does not allow identification of a specific product and neither traceability nor security functions, but applications require both, unique item identification in a backward compatible manner AND access to information via Internet.

DIN WG NA 041-01-31 responded to the initiative from Industry & Healthcare experts for a "Light IoT" system developing DIN SPEC 16589 Product to Internet Communication (Pointer to Process- P2P).

The key of the solution is an add on to any unique item bar code or RFID Tag, like a UID according to ISO/IEC 15459 using ASC DIs, e.g. DI "25S". This unique item code will be applied by an 'add on', consisting of the ASC P2P DI "34L" and a port URL. Access to the related IoT address will be executed generating the IoT target URL by extracting the P2P URL and appending the item code at the end of the P2P URL.

This is forming the Internet compatible Target URL. The formatting and converting has been standardized by registration of the ASC DI "34L". DIN SPEC 16589 describes the application of the quick and easy IoT by help of smart phone (Fig 8), by a scanner or by help of a data entry software tool.

The backward compatible Quick IoT solution using "Pointer to Process (P2P)" is smart because the item code can be used for item identification AND for IoT access. In addition to it, no additional third-party web services are required, the labeler can target the URL to information or dialogs hosted by himself. Fig. 8) is showing the principle of a P2P IoT application enabling easy access to Material Safety Data Sheets (MSDS), to maintenance instructions, to a dialog for e.g. a repair or maintenance process and many other features the Internet would allow to use.

The P2P solution is included in "DIN 66277 Electronic nameplate", also IEC TC 91 integrated P2P in IEC 62090, Edition 2.0. for automated access to product-relevant information.

Note: For information on DIN SPEC 16589 product-to-Internet communication, see:

<https://www.din.de/de/mitwirken/normenausschusse/nia/din-spec/wdc-beuth:din21:288399037>

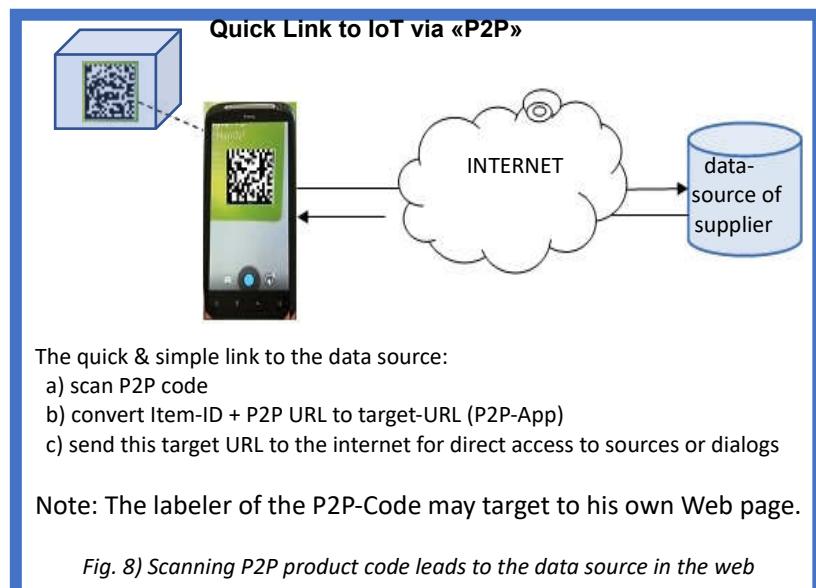


Fig. 8) Scanning P2P product code leads to the data source in the web

AIDC- Web and keyboard compatible encoding

Guideline for simple keyboard and WEB interface compatible syntax for AIDC media

Data in AIDC media get structured in order to become globally unique. Structuring is specifically required in case of multiple, concatenated data elements in a code. There are structures available using keyboard compatible character sets only, like HIBC, ISBT, Eurocode, but other structures are using extended character sets like ISO/IEC 15434 and like GS1. GS1 defines the "Group Separator (^S)" as delimiter between data elements and ISO/IEC 15434 is using complex start and stop sequence containing non-keyboard characters and "G" is defined as separator between data elements. These control characters don't pass keyboard interfaces.

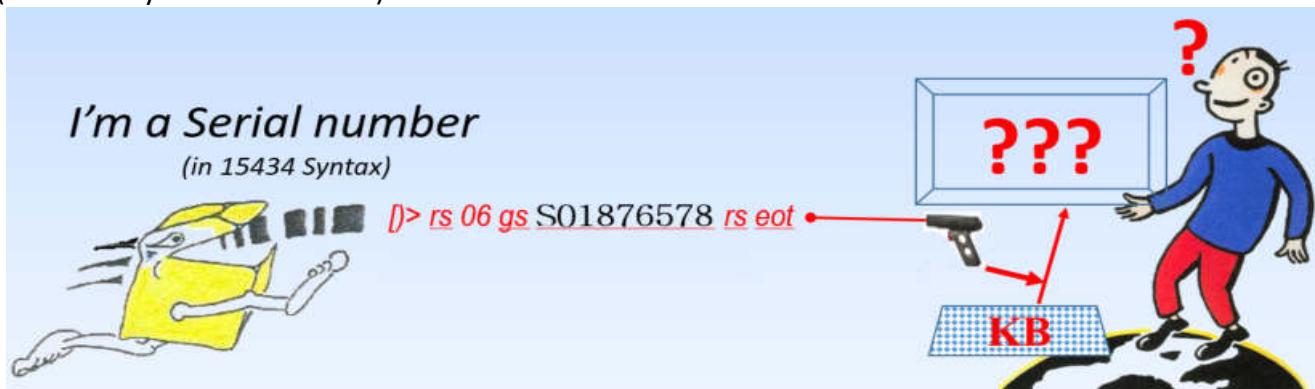
Problem to solve: "Non printable characters" don't pass Web and keyboard interfaces

Example – Processing an encoded string structured according to ISO/IEC 15434:

Advantages of this approach are that these sequences never appear "unintentionally". The disadvantage of this complex data structure is that the non-printable characters are lost in keyboard and web interfaces. At the time when ISO/IEC 15434 was created in 1995 by CEN TC 225, serial interfaces and POS interfaces were still common for handling such data structures. In the meantime, these interfaces hardly play a role anymore, so with today's standard hardware and software of keyboard emulation via USB and web applications, the implementation of e.g. ISO/IEC 15434 is a big challenge.

The problem

(the non keyboard characters)



Report Fig. 9) Problem to be solved: Captured data encoded with "non keyboard characters" do not pass keyboard interfaces

The Solution

To avoid interface problems the "EDIFICE Guideline for Web and keyboard compatible encoding with ASC Data Identifiers" defines the "." (dot) as the flag for following ASC DI data elements and as delimiter the character Circumflex "^". Both are keyboard characters and enable easy scanner and Web connectivity for all kind of interfaces.



Report Fig. 10) The solution: The Flag Character "(dot)" makes the barcode data unique and passing keyboard & web interfaces

An excerpt from the "EDIFICE Guideline for Web and keyboard compatible encoding with ASC Data Identifiers" can be found below.

The guideline is under way to "DIN 16598 Syntax keyboard and Web compatible encoding of data elements in machine readable symbols applied with ASC Data Identifiers".

===== Excerpt of the EDIFICE Guideline =====

WEB AND KEYBOARD COMPATIBLE ENCODING WITH ASC DATA IDENTIFIERS - Issue 1.0

Although the background of EDIFICE is the High-Tech Industry, the application of
this guideline is not limited to a specific industry sector or subset of Data Identifiers.

1.2 Problems to Solve

1.2.1 Ambiguity of data elements applied with ASC Data Identifiers without any Flag Character

Data elements headed by ASC Data Identifiers are not secured against overlapping with encoded data of other nature or other structurers like "IUID" headed by Text Element Identifiers (TEI).

1.2.2 Non-Web/Keyboard compatibility of ISO/IEC 15434 Syntax

Unique syntax using control characters outside the keyboard set, like ISO/IEC 15434 Syntax for high capacity media (<rs>, <gs>, <eot>, etc) do not pass such physical or virtual interfaces and may even invoke unwanted functionalities that may be assigned to corresponding keys by the application.

1.3 **The scope of this guideline** is the definition of a unique encoding scheme of data elements applied with ASC Data Identifiers for use in applications where Web and keyboard compatible syntax is required and unambiguity compared to non ASC DI data elements.

3.1 Flag and separator characters and rules

- The Flag-Character is the "." (dot) character: this is the very first character of the data string.
- All data elements are headed by ASC Data Identifiers.
- Data elements shall not contain a "^" (circumflex) character.

If more than one data element is encoded in the same symbol, then the data elements are separated by a “^” (circumflex) character.

3.4 Summary

The table below gives a summary for the usage of the dot character as flag character.

EDIFICE Table 1 - Summary

FLAG CHARACTER	EXPLANATION
.	The “dot” character is the flag character to identify Web and keyboard compatible encoding with ASC Data Identifiers. The separator between encoded data elements is the character “^” (Circumflex)

4.1 Keyboard friendly application example with unique serial number

The example in figure 11) shows a globally unique serial number with flag character “.” identifying a SN of a test tube.

Figure 11) UIM on a test tube applied with flag character “.” → (for unique distinction with other 25S... values)



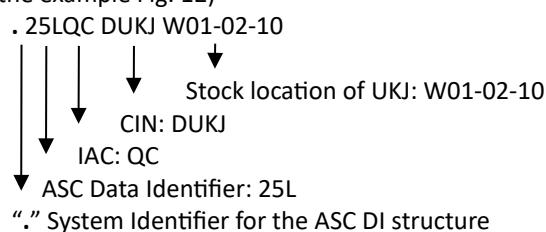
4.2 Keyboard friendly application example of a stock location code

Figure 12 below shows a warehouse applied with stock location codes.



Figure 12) - Stock location code (source: Klinikum of the Friedrich Schiller University of Jena (UKJ), Germany)

Data sequence of the example Fig. 12)

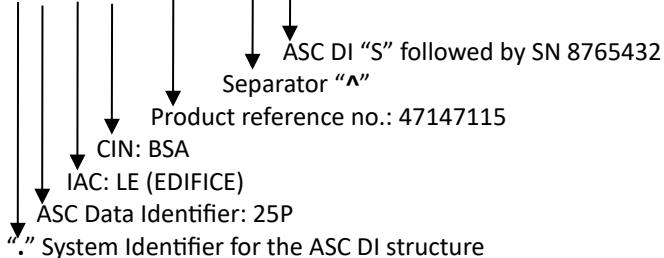


4.3 Keyboard friendly application example with two concatenated data elements Product

Fig. 13) Syntax encoded with linear barcode CODE 128 →

Data sequence of the example Fig. 13)

.25P LE BSA 47147115^S8765432



Note: The EDIFICE License Plate Guideline for Transport Units issue June 2020 included the “dot” as well, shown with the sample:

- nJ LE XYZ 1234567890

Both documents can be obtained free of charge from: <http://wp1.edifice.org/guidelines/adc/>



Appendix “Symbologies”



Data Matrix rectangular extension: “ISO/IEC 21471 DMRE”

After submission of the DIN Norm DIN 16587 DMRE to ISO, SC31 delegated it to WG1 to produce an ISO/IEC standard for extension of the regular Data Matrix features in terms of sizes and capacities for accommodation of more data on narrow or round surfaces (Fig. 14).



*Fig. 14) DMRE on medical devices applied with a UDI Health Industry Bar Code - HIBC as UDI data content
(Source: Sprague Ackley, Honeywell) and DMRE with IUID data on a round surface of a tube (Source Harald Oehlmann)*

ISO/IEC 16022 Data Matrix included 6 rectangular sizes already, DMRE provides additional 18 sizes. Some samples see table 1) for full list of sizes see www.dmare.info.

The project has been numbered with ISO/IEC 21471. Industries like Pharmaceutical Industries, Electronic Industries, Automotive and others supported the project in order to fill gaps of marking options to be applied to small form factors. ISO/IEC 21471 DMRE is available by ISO → <https://www.iso.org/standard/70947.html>

Table 1) Four examples of the 18 rectangular formats of ISO/IEC 21471 DMRE, enabling encoding of higher data volume on surfaces of small height.

Table 1) Four of the 18 rectangular extensions of Data Matrix with their ratio of size and data capacity

	Format Capacity n/an	mm x mm X=10mil/ 0,25mm	Sample with generic example data as content ▼
1	8x48 36/25	2 x 12mm	 123456789012345678901234567890123456
2	8X64 48/34	2 x 16mm	 123456789012345678901234567890123456789012345678
3	12 x 64 86/63	3 x 16mm	 123456789012345678901234567890123456789012345678901234567890 1234567890123456
4	16 x 64 124/91	4 x 16mm	 123456789012345678901234567890123456789012345678901234567890 123456789012345678901234567890123456789012345678901234
			For all DMRE-formats see table 3) or ISO/IEC 21471

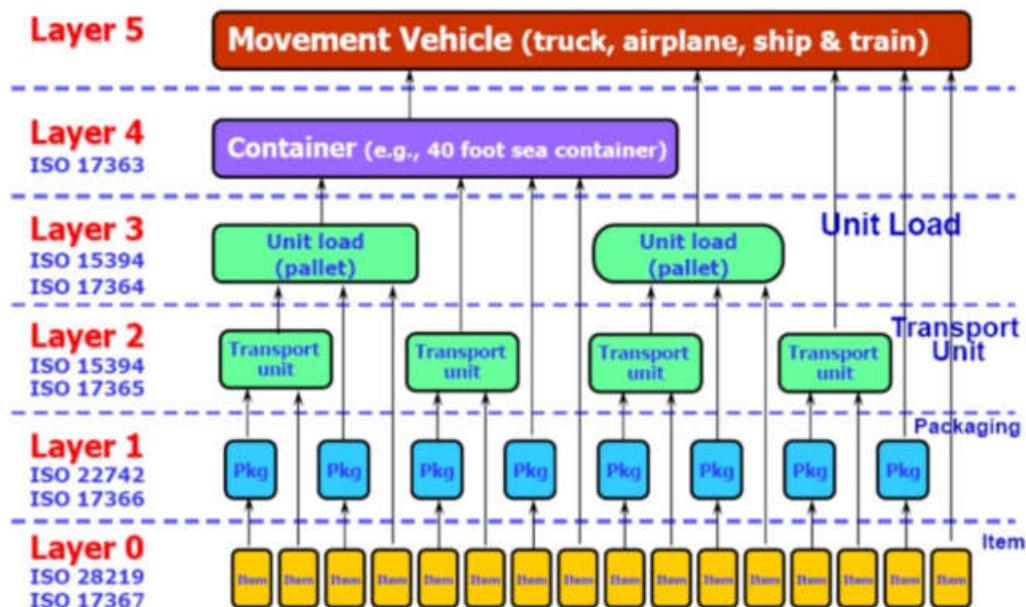
The full list of 24 rectangular symbol sizes of both ISO/IEC 16022 Data Matrix (6 sizes) and ISO/IEC 21471 DMRE (18 sizes) can be seen under www.dmare.info as freely downloadable open source tools for creating DMRE symbols.

Appendix Barcode+RFID standards

Companies obtaining a CIN can use the compatible Barcode and RFID application standards in an unlimited way. Within the standards the identifiers determine the content of coded data fields and the CIN tells to whom the data belong to.

RFID application standards go along with the bar code application standards on the four logistical levels (see Fig. 24) of AIDC report, part 2019 update) but remain under the responsibility of ISO TC 122 (secretariat Japan).

Fig. 24) is showing how the four key RFID applications standards aligns with equivalent barcode standards for the different logistical levels.



Report Fig. 24) ISO standards AIDC for the logistical levels of supply chains (C.Harmon)

The Barcode and RFID application standards reference to the relevant data syntax and data carriers harmonised for global use cross industries and cross countries.

Selection of AIDC technology and application standards

Comprehensive document

ISO/IEC 19762 Harmonized Vocabulary, 5 languages (+ Japanese under work)

Documents of ISO/IEC JTC 1/SC 31/WG 1 Data Carrier

ISO/IEC 15417 Code 128

ISO/IEC 15438 PDF 417

ISO/IEC 16022 Data Matrix

ISO/IEC 18004 QR Code

ISO/IEC 15415 Bar code symbol print quality test specification-Two-dimensional symbols

ISO/IEC 15416 Bar code symbol print quality test specification-Linear symbols

ISO/IEC 16480 Reading and display of ORM by mobile devices

ISO/IEC 30116 OCR Quality Testing

ISO/IEC 21471 Extended Rectangular Data Matrix DMRE

Documents of ISO/IEC JTC 1/SC 31/WG 2 Data Structure"

ISO/IEC 15418 GS1 Application Identifiers and ASC MH 10 Data Identifiers and maintenance

ISO/IEC 15434 Syntax for High-Capacity ADC Media

ISO/IEC 15459 Unique Identification, Part 1 to 6

ISO/IEC 29162 Guidelines for using ADC Media (Bar code & RFID)

ISO/IEC 29161 Unique Identification for IoT

ISO/IEC 20248 Unique identification for the Internet of Things



Selection of AIDC technology and application standards, continued

Documents of ISO/IEC JTC 1/SC 31/WG 4 RFID for Item Management

ISO/IEC 18000-1 REV 1 (including Battery Assistants, Sensor functions)
ISO/IEC 18000-2 AMD 1 (including Battery Assistants, Sensor functions)
ISO/IEC 18000-6, part 61 to 64, rev. 2 (incl. Battery Assistants, Sensor functions)
ISO/IEC 18000-7 REV 1 (including Battery Assistants, Sensor functions)
ISO/IEC 15963 Tag ID: applied with the list of IC manufacturer IDs
ISO/IEC 29160 RFID Emblem
ISO/IEC 24791-Part 1 to 6 Software System Infrastructure (SSI)
ISO/IEC 24753: RFID & Sensors with reference to IEEE 1451.7
ISO/IEC 15961, 15962: RFID Data protocol – Update
ISO/IEC 15961-4: Sensors commands (NP)
ISO/IEC 29172-19179 Mobile item identification and management
ISO/IEC 29143 Air Interface Specification for Mobile Interrogators



Documents of ISO/IEC JTC 1/SC 31WG 4/ RFID Security on Item Management

ISO/IEC 29167 Air Interface for file management and security services for RFID
ISO/IEC 29167 part 10-19 crypto suites with ISO/IEC 19823-X Conformance test methods



Documents of Liaison ISO TC122/WG 10 for BC&RFID applications

ISO 22742 Linear bar code and two-dimensional symbols for product packaging
ISO 28219 Labeling and direct product marking with linear bar code and 2d- symbols
ISO 15394 Bar code and 2d- symbols for shipping, transport and receiving labels
ISO 17363 Supply chain applications of RFID – Freight containers
ISO 17364 Supply chain applications of RFID – Returnable transport items
ISO 17365 Supply chain applications of RFID – Transport units
ISO 17366 Supply chain applications of RFID – Product packaging
ISO 17367 Supply chain applications of RFID – Product tagging

DIN Standards

DIN 66401 Unique Identification Mark – UIM
DIN 66403 System Identifiers
DIN 66277 Identification plate with RFID tag and/or 2D bar code
DIN 16587 DMRE - Data Matrix Rectangular Extension
DIN Spec 16589 Product to Internet communication - Pointer to Process
DIN 16598 Syntax keyboard and Web compatible encoding of data elements in machine readable symbols applied with ASC Data Identifiers (public for comments 2020-10-15)

Other relevant AIDC and Application standards

CEN 1573 Multi-Industrie-Transport Label, www.din.de
IEC 62090 Product Package Labels for Electronic Components using Bar Code & 2-d symbologies
Global Transport Label V3, www.odette.org
Global Guideline for Returnable Transport Item Identification, www.aiag.org
GS1 Global Specifications, www.gs1.com
HIBC Health Industry Bar Code, www.hibc.de
PaperEDI-Standard, www.eurodatacouncil.org
EDIFICE-Guideline WEB AND KEYBOARD COMPATIBLE ENCODING WITH ASC DATA IDENTIFIERS, www.edifice.org

Note: ISO, CEN and DIN standards are also available from all national institutes, e.g. via www.din.de

Appendix The UDI Book



Figure 15) UDI book cover sheet

On 26 September 2014, the law for barcodes on every medical device (UDI) came into force in the USA; on 5 April 2017, the corresponding EU regulation for Europe was published. Due to the penetration of these projects for the entire healthcare supply chain, DIN/BEUTH-Verlag published the reference book "UNIQUE DEVICE IDENTIFICATION" on 16 May 2017. The publication date matches the publication date of the Medical Devices Ordinance (MDR), in which "UDI" is integrated as a core element. The book provides instructions for UDI-compliant labelling for the manufacturer, but also informs users in hospitals how they can benefit from the legal requirements for UDI, because UDI is intended to

increase patient safety and efficiency for all parties involved. With UDI, legislators are aiming for 100% barcodes for all medical devices. This will motivate users to implement AIDC in all areas where error-free recording is required. The book is written in German language.

URL to the book: <https://www.beuth.de/de/publikation/udi-unique-device-identification/320019099>

URL to the MDR and IvDR: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>



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