

# AIDC supported clinical processes

## Hygiene process for instruments



Rev. 2013-11-15



# AIDC supported clinical processes

## - Hygiene process for instruments -

### History

This document has been developed and will be maintained by the Joint Technical Committee AIDC. Ongoing updates are reserved. The following developments were made:

Date	Action
13-02-08	First draft by Joint Working Group
13-10-15	Final document

### Forward

The technical specification "AIDC supported clinical processes - Hygiene process for instruments from cleaning to sterilization" has been developed by the Joint Working Group AIDC consisting of members of the associations EHIBCC, SPECTARIS, VDDI and experts from the ranks of manufacturers of sterilization systems and under contribution of users.

By help of this specification local systems (islands) shall become interoperable with each other for building interconnected and compatible systems as part of a whole for error free data capture from beginning to end of a chain. The use of AutoID includes potential for optimizing systems reasonably where the responsibility for the process itself remains with the system designer and user.

## Content

1 Scope .....	3
2 Terms & abbreviations.....	3
3 Introduction .....	4
4 Uniqueness .....	4
5 Data elements with relevance to automatic identification.....	5
6 Data elements, assignment to the process.....	7
7 Data structures and symbols .....	14
8 Direct marking of plates, containers, instruments .....	17
9 Anex Bibliography .....	18

# 1 Scope

The technical specification „AIDC supported clinical processes - Hygiene process for instruments - “ contains definitions for designing the unique data elements and coding schemes required for automatic identification and data capture (AIDC) for optimizing processes and avoiding errors. It covers the processes around medical products, instruments, equipment and accessories from delivery at the Entry Point to logistic handling, usage, maintenance, repair and adjacent cycles (see chart 1).

This specification is based on the relevant ISO, HIBC and DIN standards for automatic identification and defines data elements and codes for unique data capture at any step of the processes and its documentation. The specification does not determine specific sequences of steps but supplies the means for unique data capture of any individual step. Given processes might not be changed rapidly but can be optimized and secured by integrating recommended modules step by step. The selection of the proposed data elements is subject to the conditions of each application under the responsibility of the user as system designer or system integrator. Appropriate barcode labels are included for illustration as samples for tracking and tracing items and processes over the requested cycle and/or for the whole system.

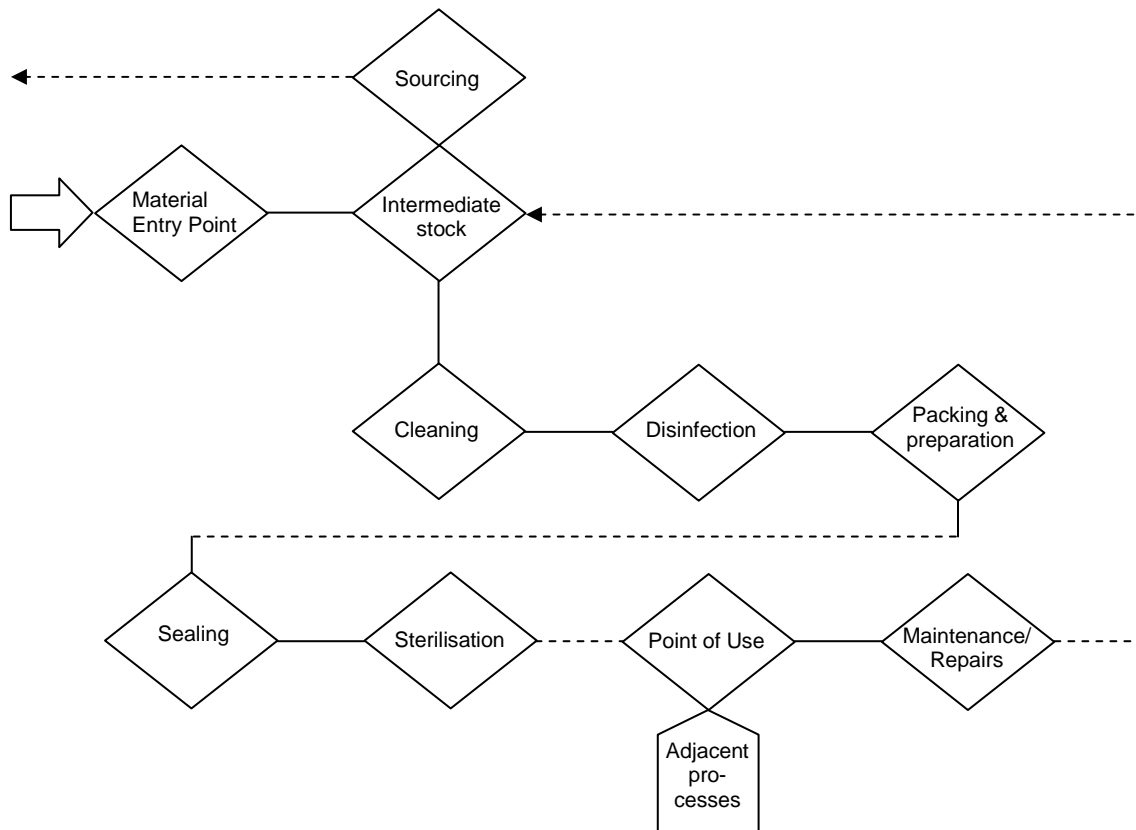


Chart 1) Coverage of AIDC supported clinical processes - Hygiene process for instruments -

## 2 Terms & abbreviations

ASC	Accreted Standards Committee
Company Identification Number (CIN)	Unique company or labeler ID issued by an Issuing Agency according to ISO/IEC 15459 and key for unique labeling of any item in a process chain, e.g.: ELMI
GS1	Global Standards One
HIBC	Health Industry Bar Code
Issuing Agency	Agency for issuing unique CINs according to ISO/IEC 1549, e.g. EHIBCC
Issuing Agency Code (IAC)	Registered Code of the Agency according to ISO/IEC 15459 e.g. „LH“ for EHIBCC (in unique bar codes proceeding a CIN, e.g. “LHELMI”, see PIC)
KIT	Container or tubular bag content building a kit
KIT Data Matrix	Data Matrix with encoded content of a KIT applied to containers, bags, etc. and structured according to the coding scheme of the standard “HIBC Standard PaperEDI”
Labeler Identification Code (LIC)	Unique Labeler Code registered by Issuing Agency EHIBCC (see CIN)
Sterilization Batch No.	Reference no. for the sterilization process
Partner Identification Code (PIC)	Combination of IAC and CIN (e.g. LHELMI). The PIC is the first data element of unique ASC DI data construct, e.g. “25S”, “25B”, “25P”, etc.
PPN	Pharma Product Number
Program ID	Control code for setting parameters (program) of specific equipment
Sealing Batch No.	Reference no. to batches of sealings getting one common clearance
Sealed Bag ID	Reference no. to a bag to be sealed or sealed bag
Sterilization Container ID	Reference No. to a container, basket, etc.
SN	Serial Number
UIM	Unique Identification Mark according to HIBC UIM, DIN 66401

### 3 Introduction

Concatenated processes, like processes around the live cycle of surgical instruments, require correct and error free documentation. Here, the same methods and technologies are appropriate as at all other data entry points for error-free data capture in the supply chain and in clinical processes. The use of two-dimensional barcode and its options has proven to deliver excellent results.

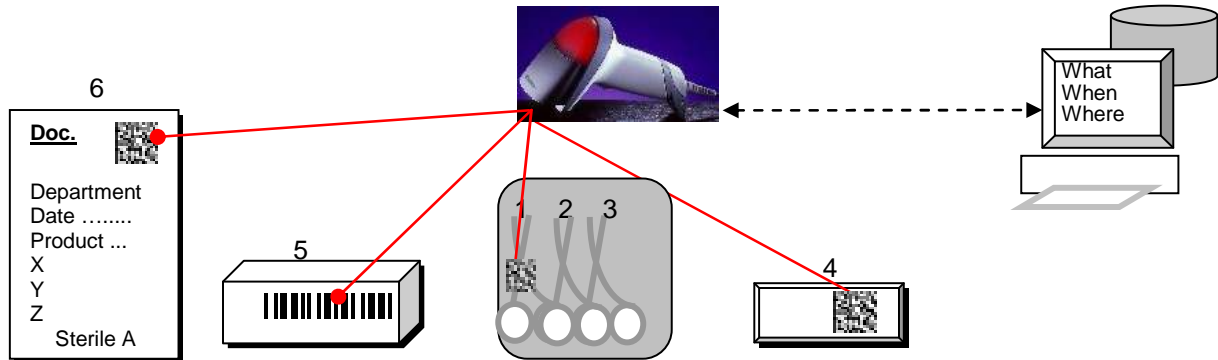


Fig. 1) Bar code for error-free data capture and key IDs:

- 1-3) Instruments
- 4) Container, Basket, Sealed Bag/Package
- 5) Unit (Sealing Unit, Sterilization Unit, Operating Facilities)
- 6) Document/Order
- 7) Person
- 8) Room/Location, etc.

There are different symbologies available to carry the data elements. This document is showing solutions with the linear symbologie ISO/IEC 15417 Code 128 and the two-dimensional code ISO/IEC 16022 Data Matrix. Radio Frequency Identification technologies (RFID) are available as additional options where appropriate and can be used as an option or in parallel to optical codes. The advantage of Data Matrix is the capacity, small sizing and availability of a variety of print and reading equipment.

### 4 Uniqueness

First, the data elements are to be defined, which are necessary for (automatic) Identification. ASC Data Identifiers and HIBC product codes supply the necessary features for marking any individual item uniquely but also data elements belonging to the process as attributes. The simple rule to make an internal but unnamed data element globally unique is to add the appropriate Data Identifier (DI) to the data itself. By using DIs the computer will recognize the content of a code automatically after scan. Data Matrix supplies the capacity to concatenate multiple data elements and hierarchical structured information. For concatenated information the "data container" ISO/IEC 15434 Transfer Syntax will be used.

*Note: Unnamed reference numbers cannot be identified uniquely outside a closed system where the meaning of the number is unknown. Example, what is behind: 1234567890? Furthermore such "generic" numbers can overlap with numbers of adjacent systems or external systems dropping in scanning areas as well. DIs solve this problem. Applied with a DI that number would be globally meaningful. Does 1234567890 represent a serial number then the DI "S" will be add: S1234567890. The Data Identifiers are selected from the standardized list of ISO/IEC 15418 – ANS MH 10.8.2, part ASC DIs. Included is the System Identifier „+“ for the Health Care Bar Code HIBC. Additional Identifiers can be selected on demand as subject of maintenance for this document.*

## 5 Data elements with relevance to automatic identification

Process relevant data elements for automatic identification can be classified into 3 different categories:

- A) Items, physical objects like products, instruments, units, equipment, etc.
- B) Persons, partners/companies/institutions
- C) Process references like orders, listings, sequences, parameters, attributes

Table 1 shows relevant data elements put in the order of the 3 categories. Any data element is applied with an ASC Data Identifier supplying the correct meaning for the computer.

Data elements with Partner Identification Code (PIC), e.g. DI "25S" for unique serial numbers are globally unique. A serial number without PIC will get the DI "S" and will be unique only inside the system where this SN was generated.

Data elements and DI constructs shall be selected from table 1 according to the requirements of internal or global uniqueness. Requirements for global uniqueness applies also if more than one internal systems are involved which are not connected, e.g. one system is printing a label, the other system gets the scanned data.

Table 1) Data elements and applied Data Identifiers

\*K.L.: KIT level: See chapter 6.3 ▼

Category/Description	Content and example data	DI	Example of data element	*K.L.
<b>A – physical items</b>				
Instrument, serialized	Globally unique Serial Number (SN) <b>99999999</b>	25S	25SLHELMI <b>99999999</b>       DI PIC SN	X,I
	Internally controlled SN <b>99999999</b>	S	S <b>99999999</b>     DI SN	X,I
Instrument with LOT no. (several instruments with same LOT no.)	Globally unique LOT <b>12345ABC</b>	25T	25TLHELMI <b>12345ABC</b> Structure like 25S, but with DI for LOT	X,I
	Internally controlled LOT <b>12345XYZ</b>	1T	1T <b>12345XYZ</b>     DI LOT	X,I
Instrument with product REF +SN	HIBC Code, serialized, globally unique, example data LIC: "ELMI", Product REF: <b>776633P</b> , Unit of Measure: "0", SN: <b>99999999</b>	+	+ELMI <b>776633P0/\$+99999999L</b>                 LIC Prod. control SN   L=check ch.	X,I
	Option ASC DI structure: IAC "LH", LIC "ELMI", REF <b>776633P</b> , SN <b>99999999</b>	25P +S	25PLHELMI <b>776633P+S99999999</b>                 DI PIC Produkt DI SN	X,I
Instrument, product REF only	Globally unique product code HIBC (Primary code)	+	+EHIBCMEDIX <b>1201</b>	X,I
	Internally controlled product REF	1P	1 <b>P</b> MEDIX <b>12</b>	X,I
Container/Sieve/Bag	Globally unique applied with SN	25B	25BLHELMI <b>9999999999</b>       DI PIC SN	P
	Internally controlled container SN	1B	1 <b>B</b> <b>9999999999</b>	P
Units & equipment/assets (Sealing units, machines, ...)	Internally controlled SN <b>88888888</b> without type/product ref.	S	S <b>88888888</b>	P
	Unique HIBC applied by manufacturer, serialized, product example: <b>MEDIX12</b>	+	+HIBCMEDIX <b>120/\$+999999997</b>	P
Accessories	Marking like units or instruments			
Consumable supplies	HIBC Code			
Location/Room/Position	Location code <b>ABC456</b>	1L	1 <b>L</b> <b>ABC456</b>	P
	Globally unique Location ID with "PIC"	25L	25 <b>L</b> <b>QCELM</b> ABC456	P

Tabelle 1 continued

Category/Description	Content and example data	DI	Example of data element	*K.L.
<b>B) Personal &amp; Partner ID</b>				
	Global Personal ID <b>1234567</b> Internal Personal ID: <b>1234567</b> Internal Person: <b>First name</b> Internal Person: <b>Family name</b>	25H 1H 11H 5H	25HLHELMI <b>1234567</b> 1H <b>1234567</b> 11H <b>FIRSTNAME</b> 5H <b>FAMILYNAME</b>	P
Partner/Company ID	Globally unique Company ID	18V	18VLHELMI	P
<b>C) Process References</b>				
Order ID	Order number: <b>7890A22</b>	1K	1K <b>7890A22</b>	P
Partner ID	Globally unique Company/Partner ID	18V	18VLHELMI	
CLEANING Batch	Cleaning Batch: <b>123XYZ</b>	30T	30T <b>123XYZ</b>	P
DISINFECTION Batch	Disinfection Batch: <b>123XYZ</b>	31T	31T <b>123XYZ</b>	P
*Batch - generic	Batch, individually defined	32T		P
SEALING Batch	Sealing Batch: <b>123XYZ</b>	33T	33T <b>123XYZ</b>	P
STERILIZATION Batch	Sterilization Batch: <b>45F40</b>	34T	34T <b>45F40</b>	P
Sub-process/Process step	e.g.. drying (around disinfection): <b>2</b>	1W	1W <b>2</b>	P
Manufacturing date	Format: JJJJMMDD	16D	16D <b>20130212</b>	P
Expiry date	Format: JJJJMMDD	14D	14D <b>20160211</b>	P
Program Code	Program Code: <b>1356Y</b>	2W	2W <b>1356Y</b>	P
<b>Parameter values</b>				P
	Sealing time (Seconds)	7Q_03	<b>Q9903</b> (for 99 seconds)	P
	Sealing temperature Centigrade Celsius)	7Q_CE	<b>7Q100CE</b> (for 10 degr. Celsius)	P
	Sealing pressure (Newton): <b>100</b>	7Q_UN	<b>7Q100UN</b>	P
	Voltage value (Volt): <b>1,4Volt</b> (Comma encoded as Dot)	7Q_VT	<b>7Q1.4VT</b>	P
KIT info in doc/ product code	KIT mark „KI“	12PKI	<b>12PKI</b>	P

<b>D) Data Grouping</b>				
Grouping data elements in a KIT Data Matrix	KIT code hierarchically structured bundled information (e.g. content of a container)	F	See chapter 7.4 „Grouping“	
<b>E) System Identifiers</b>				
Dot „ . “	ASC System ID for single codes	.	.S1234567	
Macro 06	Data Matrix control character for Syntax ISO/IEC 15434	Macro06	(see chapter 7.3)	
FNC1	GS1 System ID for Application Identif.	FNC1	<b>FNC10102012345123458</b>	

\*Note: Originally intended for marking PACKS (Pack Lot) but usage to be defined for specific application.

## 5.1 Syntax of KIT Codes, respectively PaperEDI Codes

Products can be delivered with different numbering schemes and codes, e. g. with HIBC, GS1, PPN, etc. structures. All of those standardized structures are compatible. Even so, data elements encoded in one of the structure can be converted to another structure without losing the data information, if the appropriate Identifier is available. For generating KIT Codes and P'EDI Codes the ASC DI structure is applicable because all of the necessary DIs and control characters are available specifically for grouping data information. Table 2 shows examples of different notations for data elements and conversion to the ASC DI structure.

Table 2) Different codes for physical items converted from structure X to ASC

Item ▼	Delivered with structure ▼	*SI ▼	number in structure X ▼	DI ▼	ASC structured (converted) ▼
Product	HIBC Primärcode	+	+ELMI1234513	.25P	25PLHELM112345
	GS1-GTIN	FNC1 01	FNC10102012345123458	.8P	8P02012345123458
	PZN (Pharma Zentral Nr.)	-	-1234567	.9N	9N1112345678CC
UIM	GS1-GIAI (Global Individual Asset Identifier)	FNC1 8004	FNC1800412345671234567	.25S	25S12345671234567

\*SI = System Identifier according to DIN 66403 and ISO/IEC 15418-ANS MH 10.8.2

## 6 Data elements, assignment to the process

This chapter describes the application of the Data elements and its DIs of table 1 assigned to specific process steps. Described process steps are taken from practical examples but any other variation might need other data elements or may not need specific elements because of different process design.

### 6.1 Sourcing & inventorisation of medical devices and equipment

It is recommended to purchase medical devices and equipment which has been marked already uniquely by the manufacturer according to ISO 28219, DIN 66401 or DIN 66277 standard. Standardized unique codes supplied on products enable usage at any point such as goods entry, inventory and for identification within the process where the item is involved as for repair and maintenance documentation as well. Additional labeling can be avoided.

#### 6.1.1 Codes for small items like surgical instruments

For small device marking Data Matrix is recommended applied with a unique serial number according to HIBC and DIN 66401 UIM:

- if Product REF + Serial Number, then HIBC delivers compactness for smallest sizes
- if "SN" only, then globally unique SN applies (see table 3).

### 6.2 Materials ENTRY POINT

Delivery of relevant medical devices for entering in the process may come from external or from other internal areas. The whole delivery can be captured from a picking list, if the list has been applied with a Data Matrix and structured KIT or SET information (see chapter 7). A selection of relevant data elements is listed in table 3) and 4).

Table 3) Product data for capturing at the process entry point

Process step (s)	Relevant code options	DI	examples
Goods entry, intermediate stocking, treatments, maintenance, repair, etc.	Product/Unit serialized	+	HIBC-Code, incl. SN +ELMIMED11/\$+123456
	or	25P+S	25PLHELMIMED11+S123456
	Globally unique SN only	25S	25SELMI123456
	Unit REF without SN	+	HIBC Primary Code
	or	25P	25PLHELMIMEDIX22
	(See also table 1)		



Table 4) delivery data for capturing at the process entry point

Process step (s)	Relevant code options	DI	examples
Receiving packing list/shipment note	ID of list + globally unique partner ID(PIC)	11K 18V	<b>11K</b> 3456542 <b>+18V</b> LHELMI
	Internals packing list ID	11K	<b>11K</b> 2345432
Identifying materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
<b>Option</b>			
Capturing delivery from a Data Matrix on picking list/shipment note	Header data and product data of the delivery see chapter 7.4 „Grouping“ and HIBC Standard „PaperEDI“	F	Level „T“ (TARE) Level „O“ (ORDER) Level „P“ (PACK) Level „I“ (ITEM) Level „X“ (SERIAL)

### 6.3 CLEANING

For CLEANING specific batches of materials will be created, the Cleaning Batches. This batches can be communicated by ERP system or add to as data element in a Data Matrix.

Table 5) Data elements CLEANING process

Data capture of/process step	Relevant code options	DI	examples
Order	Internal order ID	1K	<b>1K</b> XYZ
	Order ID + globally unique PIC	1K 18V	<b>1K</b> XYZ <b>+18V</b> LHELMI
ID of packing list	See table 4		
Container/Basket	With globally unique SN	25B	<b>25B</b> LHELMI99999999
	With internal SN	1B	<b>1B</b> 99999999
Option: Identifying single materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
Location	Location code internal	1L	<b>1L</b> 123XY
	Location code globally unique	25L	<b>25L</b> LHELMIABC789
ID Personal	Personal ID globally unique	25H	<b>25H</b> LHELMI123XYZ
	Personal ID internal	1H	<b>1H</b> 123XYZ
Unit/Equipment/Inventory No.	Unit ID globally unique	+	HIBC-Code incl. SN
	Globally unique SN of unit	25S	<b>25S</b> LHEMED1234567
	Unit REF without SN (HIBC Primary Code)	+	+ELMIMED12\$
	Unit REF without SN (ASC)	25P	<b>25P</b> LHELMIMEDIX22
	Internal Unit REF	P	<b>P</b> TYP11
Generating CLEANING BATCH (e. g. at label printing step)	CLEANING Batch	30T	<b>30T</b> 123ABC

## 6.4 DISINFECTION

The disinfection process can have its own batch number. For this purpose the following unique data elements are defined:

Table 6) Data elements DISINFECTION

Data capture of/process step	data elements (globally or internally unique)	DI	example
ID of packing list / delivery note	See table 4, ID of list		
Location	Location code internal	1L	<b>1L</b> 123XY
	Location code globally unique	25L	<b>25LL</b> HELMIAABC789
Container/Basket	with globally unique SN	25B	<b>25BL</b> HELMI99999999
	with internal SN	1B	<b>1B</b> 99999999
Option: Identifying single materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
Disinfection Unit	Unit D globally unique (HIBC)	+	HIBC Code incl.SN
	Unit D globally unique SN only	25S	<b>25SL</b> HELMI1234567
	Global Unit REF without SN (HIBC)	+	HIBC Primary Code
	Global Unit REF without SN (ASC)	25P	<b>25PL</b> HELMIMEDIX22
	Internal unit REF without SN	1P	<b>1P</b> DESINF22
Documenting Personal-ID	Personal ID globally unique	25H	<b>25HL</b> HELMI123
	Personal ID internal	1H	<b>1H</b> 123
Generation of the Disinfection Batch , e. g. for printing on label	Disinfection Batch	31T	<b>31T</b> 123XY

## 6.5 PACKING in Sieves / containers for sterilization

When packing for preparation of subsequent process steps, it is important to capture the content or to know the content in the database and to reference a PACKING ID with container, tray, sieve or bag.

### Option KIT code

Optionally, a KIT Data Matrix can be applied for automatic capturing of the (entire) content of the package by a scan.

Table 7) Data elements PACKING

Data capture of/process step(s)	data elements (globally or internally unique)	DI	examples
Basket/Container/Bag (tubular bag)	with globally unique ID	25B	<b>25BQC</b> FIRM99999999
	with internal ID	1B	<b>1B</b> 99999999
Option: Identifying single materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
Location	Location code globally unique	25L	<b>25LL</b> HELMIAABC789
	Location code internal	1L	<b>1L</b> 123XY
ID Personal	Personal ID globally unique	25H	<b>25HL</b> HELMI123XYZ
	Personal ID internal	1H	<b>1H</b> 123XYZ
<i>continued</i>			

<i>Continuation of table 7</i>			
<b>Option</b> KIT Code with grouped content information	See chapter 7.4 „Grouping“	F	Level „P“: Container/Bag Level „I“: contained items

## 6.6 SEALING

The data elements of the process step SEALING can be combined with the data STERILIZATION by providing data information for passing through the process in advance.

Table 8) Data elements SEALING

Process step(s)	data elements (globally or internally unique)	DI	examples
Pre-process: generation of SEALING order (paper)	Globally unique number (see table 1C)	18V	+18VLHELMI
	Internal order ID	1K	1KSIEG4567
<b>Data capture of</b>			
Order	Internal order no. (or globally unique no.)	1K	1KSIEG4567
		18V	+18VLHELMI
ID Personal	Personal ID globally unique	25H	25HLHELMI123XYZ
	Personal ID internal	1H	1H123XYZ
SEALING Unit/Equipment	Serialized HIBC Code	+	HIBC with SN
	Globally unique SN (ASC)	25S	25SLHELMI1234567
	Internal Serial Number only	S	S12345671234567
	See also options DIN 66277		E-Name Plate (+RFID)
Location	Location code internal	1L	1L123XY
	Location code globally unique	25L	25LLHELMIABC789
Responsible service partner	Globally unique Partner/Company ID	18V	18VLHELMI
Option: Identifying single materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
Generation of the Batch SEALING	SEALING Batch	31T	31T123XY

### 6.6.1 Parameter values SEALING

The code on the seal label can carry parameter values optionally if they are to be automatically captured and recorded for availability at subsequent processes (see Table 1, column values).

## 6.7 STERILIZATION

Prior to Sterilization the relevant data information will be collected for printing the final Label. The process step might be connected with the pre-process SEALING by printing the final label at the relevant step of the pre-process.

Table 9) Data elements STERILIZATION

Process step(s)	data elements (globally or internally unique)	DI	examples
PRINTING sterilization order, where appropriate, external	Internal order ID (globally unique number see table 1C)	1K 18V	<b>1KSIEG4567</b> <b>+18VLHELMI</b>
<b>Data capture of</b>			
Order	Internal order no. (or globally unique no.)	1K 18V	<b>1KSIEG4567</b> <b>+18VLHELMI</b>
ID Personal	Personal ID globally unique	25H	<b>25HLHELMI123XYZ</b>
	Personal ID internal	1H	<b>1H123XYZ</b>
STERILIZATION Unit/Equipment	Serialized HIBC Code	+	HIBC with SN
	Globally unique SN (ASC)	25S	<b>25SLHELMI1234567</b>
	Internal Serial Number only	S	<b>S12345671234567</b>
	See also options DIN 66277		E-Name Plate (+RFID)
Location	Location code internal	1L	<b>1L123XY</b>
	Location code globally unique	25L	<b>25LLHELMIABC789</b>
Container/bag (tubular bag)	With globally unique ID	25B	<b>25BQCFIRM99999999</b>
	With internal ID	1B	<b>1B99999999</b>
Option: Identifying single materials for conditioning	<i>See table 1, category A physical items and table 3 product data</i>		
Responsible service partner	Globally unique Partner/Company ID	18V	<b>18VLHELMI</b>
<b>Process step(s)</b>			
PRINTING sterilization label for the sterilized units	... if not pre-printed at the pre-process (SEALING) ↓		
a) Minimum data information	STERILIZATION Batch	34T	<b>34T45F40</b>
	Personal ID	1H	<b>1H123M17</b>
b) add. Data information	Program code / Setting code	2W	<b>2W12345678</b>
	Production date	16D	<b>16D20130212</b>
	Expiration date	14D	<b>14D20160211</b>
c) if the label shall be used externally	Partner/Company ID	18V	<b>18VLHSTRX</b>
d) for grouped data information	KIT Data Matrix see chapter 7.4 „Grouping“		

## 6.8 Sub-Steps

Within certain process steps sub-steps (e.g. DRYING) might require to be documented. A code for the sub-step will be identified by a data element applied with DI “1W”. The other data elements correspond to the characteristics of this mother step.

## 6.9 Maintenance & Repair

Existing, particularly serialized product codes, unique serial numbers can be used for control purposes and documentation of maintenance and repair processes. Additional Codes or labels can be avoided. But if no unique code is available, then one of the codes of table 1, category physical items applies.

## 6.10 Overview label content

Labels which are aligned with the subsequent processes carry data information according to the characteristics of the processes. Table 10 accentuates to 4 selected label types:

- A) SEALING Batch Label – applied with minimum data element “Batch No.”
- B) SEAL BAG ID Label applied with data information for the Sealing process
- C) STERILIZATION Label applied with data information for the Sterilization process
- D) STERILIZATION Label applied with a KIT Code

Table 10) Matrix of data elements and different label type examples

Coded data element	remark	DI	Label							
			A SE ALI NG Bat ch Lab el	B1 SEA L Bag Lab el inter nal	B2 SEA L Bag Labe l glob al	C1 STE RI Lab el inter nal	C2 STE RI Lab el glob al	D1 with KIT Cod e inter nal	D2 with KIT Cod e glob al	
SEALING Batch	for the whole SEALING Batch	33T	X	X	X	O	O	O	O	
SEAL BAG + global SN	or Container/Tray globally uniq.	25B			X		O		O	
SEAL BAG + internal SN	or Container/Tray internal	1B		X		O		O		
Items for sterilization	See table 1, category A			O	O	O	O	O	O	
Personal ID global		25H			X		X		X	
Personal ID internal		1H		X		X		X		
STERILIZATION Batch	for the whole STERI Batch	34T		O	O	X	X	X	X	
Production date		16D		O	O	X	X	X	X	
Expiration date		14D		O	O	X	X	X	X	
Program Code		2W		O	O	O	O	O	O	
Parameters	e. g. for SEALING	7Q		O	O			O	O	
Partner/Company/ Institute ID	for crossing processes	18V		O	X	O	X	O	X	
KIT Code	Content information of containers/bags	F						X	X	
<i>Legend: X = applies, O = option</i>										

## 6.11 Label examples



Fig.2) SEALING Batch label, internal, applied with Code 128

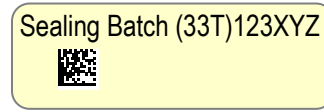


Fig.2b) with Data Matrix

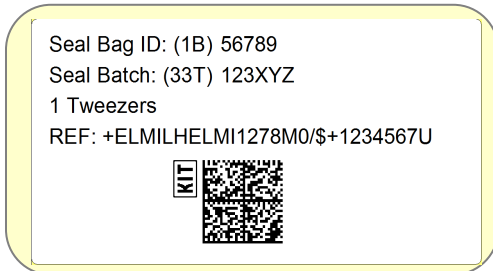


Fig.3) SEALING Bag label applied with text and **KIT** Data Matrix containing internally unique Bag ID, Sealing Batch, REF of sealed item and SN (Code structure see chapter 7.4.)

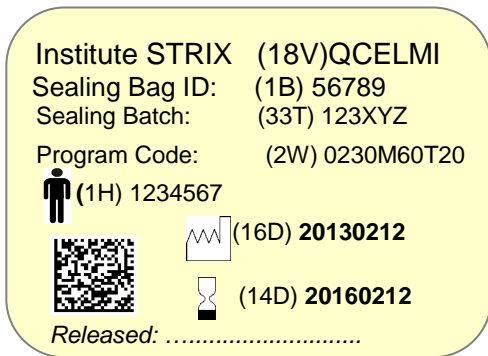


Fig. 4) Combined label covering the 2 process steps SEALING & STERILIZATION, printed at the pre-step

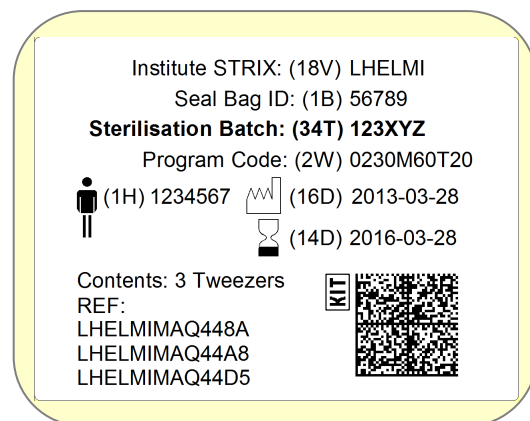


Fig. 5) Combined label, applied with **KIT** Data Matrix containing data elements for all items included (Code structure see chapter 7.4.)

## 7 Data structures and symbols

### 7.1. HIBC structure

Health Industry Bar Code (HIBC) is primarily used for medical devices. HIBC consists of two connected parts. The first part is the Primary code containing Labeler ID, REF and Unit of Measure (Packaging Level) and the second part, the Secondary code, contains the product variables such as Expiry date, LOT, SN, Quantity. The structure is most dense, Primary and Secondary code can be printed separated or concatenated.

The registered System Identifier (SI) for HIBC is the „+“.

HIBC can be printed with different standard symbologies such as

Code 39, Code 128, CODABLOCK F, QR-Code, Data Matrix or carried by RFID.

The recommended symbology is ISO/IEC 16022 Data Matrix for space saving and safety reasons.

Single data elements might be printed with Code 128 if enough space.

### 7.2. ASC Data Identifier (DI) structure

ASC Data Identifier structure is primarily used for single or concatenated single data elements. HIBC data elements can be encoded in DI structure losing compactness by winning additional capacity for additional data information like process information.

#### 7.2.1 Single data elements, Code 128 and System Identifier “. “ (dot)

Single data elements applied with DI can be printed with Code 128 if the label length is sufficient.

For increasing uniqueness it is recommended to add the System Identifier „. “ (dot) as first character of Code 128 for proceeding the DI.

Example: **.S1234**

#### 7.2.2 Concatenation of single data elements with Code 128

If enough space another data element can be connected by using “+” between the data elements as separator.

Example **.25B4567 + 34T1234**

*Note: For concatenation of data elements encoded with Data Matrix see chapter 7.3 and 7.4*

### 7.3. Concatenation of data elements and System Identifier for DATA MATRIX

For concatenation of data elements encoded with Data Matrix ISO/IEC 15434 Syntax for High Capacity Media applies. For the present application of DIs, the System Identifier and Format Header “06” applies, encoded with Data Matrix as one single control character “Macro 06”. Scanning the Syntax, the message header and terminator will be generated automatically to complete the syntax for transmission. The control characters sets are:

Header with Macro 06: [ ] >  $R_S 06^G_S$

Group Separator:  $G_S$  (separates multiple DI headed data elements)

Record Separator:  $R_S$

End of Transmission:  $E_{OT}$

Example of a concatenated data string structured with syntax ISO/IEC 15434:

a) encoded in Data Matrix: “Macro 06” DI Data  $G_S$  DI Data  $G_S$  ..... DI Data

b) transmitted by scanner: [ ] >  $R_S 06^G_S$  DI Data  $G_S$  DI Data  $G_S$  ..... DI Data  $R_S E_{OT}$

*Note: see also Fig. 6)*

### 7.4. Grouping of data elements for „KIT Codes”

The capacity of Data Matrix enables encoding of higher data volumes. The code size will grow with the data volume. Grouping allows hierarchically structured data information by help of the Data Identifier “F”. Detailed rules are described with the standard “HIBC PaperEDI”. This method is used for building Content Codes of packing lists, shipment advises, Set and KIT Codes. One scan of such a Data Matrix allows capturing complex data information as used for Electronic Data Exchange (EDI) but by paper (label). Such codes enable access to content information at any time at any location even without connection to data bases of a system and therefor used as back up solution as well.

For structuring KIT Data Matrix on container level (Sealing Bag, Sterilization Container) the data elements will be sorted into the levels, where the following Level IDs apply (see also table 1 – KIT levels):

Container and header data: Level „P“ (Pack)

Data of contained items: Level „I“ (Item)

If multiple items of the same product REF but different SN are contained, the related Serial Numbers can be sorted to Serial Number level: Level “X” (Serial)

#### 7.4.1 Examples of data content of structured KIT Data Matrix

##### 7.4.1.1 Content SEALING LABEL

Fig. 6a) illustrates the structured content of a KIT Data Matrix in vertical sequence,

Fig. 6b) shows same data content but illustrated as Tree structure.

ID	Data	Comment
Scan no. 1		
Symbology	ld1	Datamatrix
Raw data	[ ]><rs>06<gs>F01001P<gs>12PKI<gs>1B56789<gs>33T123XYZ<gs>F02010I<gs>25PLHELMI1278M<gs>S1234567<rs><eot>	Symbology type Datamatrix passed by reader
Structure type		ADC
ADC format type	[ ]><rs>06	ISO/IEC 15434 container
ADC field separator		ADC format # 1 of type ASC: ANS MH10.8.2 DI
Level	F	<gs>
Document Type	12P	01001P
Container	1B	
Lot 4: Sealing	33T	
Level	F	
Labeller	25P	
Article		
Serial number	S	
ADC format trailer		
ADC End		
Result of last scan		
Resume		
		ADC structure Ok

Fig. 6a) Screen shot KIT DataMatrix SEALING Bag label (Fig.3)

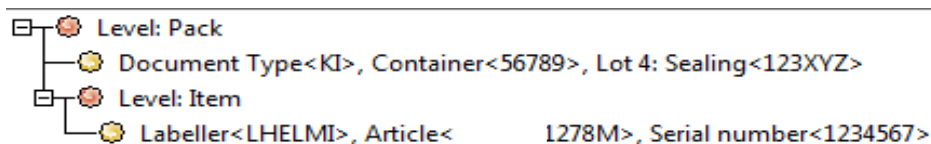


Fig. 6b) Illustration Tree structure of the KIT Data Matrix content SEALING Bag label (Fig.3)



### 7.4.1.2 Content STERILIZATION KIT Label (STERI Label)

Fig. 7a) illustrates the structured content of a KIT Data Matrix in vertical sequence, where Fig. 7b) shows same data content but illustrated as Tree structure.

	ID	Data	Comment
Scan no. 1			
Symbology	]d1	Datamatrix	Symbology type Datamatrix passed by reader
Raw data		[ ]><rs>06<gs>F01001P<gs>12PKI<gs>18VLHELMI<gs>1B56789<gs>34T123XYZ<gs>1H1234567<gs>16D20130328<gs>14D20160328<gs>F02010I<gs>25SLHELMIMAQ448A<gs>25SLHELMIMAQ448A<gs>25SLHELMIMAQ44D5<rs><eot	
Structure type		ADC	ISO/IEC 15434 container
ADC format type	[ ]><rs>06		ADC format # 1 of type ASC: ANS MH10.8.2 DI
ADC field separator		<gs>	
Level	F	01001P	Level Pack Interpreted data: ID 01 Parent 00 Child 1 Level P
Document Type	12P	KI	
Location Company	18V	LHELMI	
Container	1B	56789	
Lot 5: Sterilisation	34T	123XYZ	
Person	1H	1234567	
Production date	16D	20130328	Interpreted data: 2013-03-28
Expiry date	14D	20160328	Interpreted data: 2016-03-28
Level	F	02010I	Level Item Interpreted data: ID 02 Parent 01 Child 0 Level I
Labeller	25S	LHELMI	Elmicron Dr.Harald Oehlmann GmbH Issuing Agency: EHIBCC
Serial number		MAQ448A	
Level		%	Implicit level due to repetition of DI <25S> Interpreted data: ID 02.1 Parent 01 Child 0 Level I
Labeller	25S	LHELMI	Elmicron Dr.Harald Oehlmann GmbH Issuing Agency: EHIBCC
Serial number		MAQ44A8	
Level		%	Implicit level due to repetition of DI <25S> Interpreted data: ID 02.2 Parent 01 Child 0 Level I
Labeller	25S	LHELMI	Elmicron Dr.Harald Oehlmann GmbH Issuing Agency: EHIBCC
Serial number		MAQ44D5	
ADC format trailer		<rs>	
ADC End		<eot>	
Result of last scan			
Resume			ADC structure Ok

Bild 7a) Screen shot scanned KIT-Data Matrix STERI Label (Fig. 5)

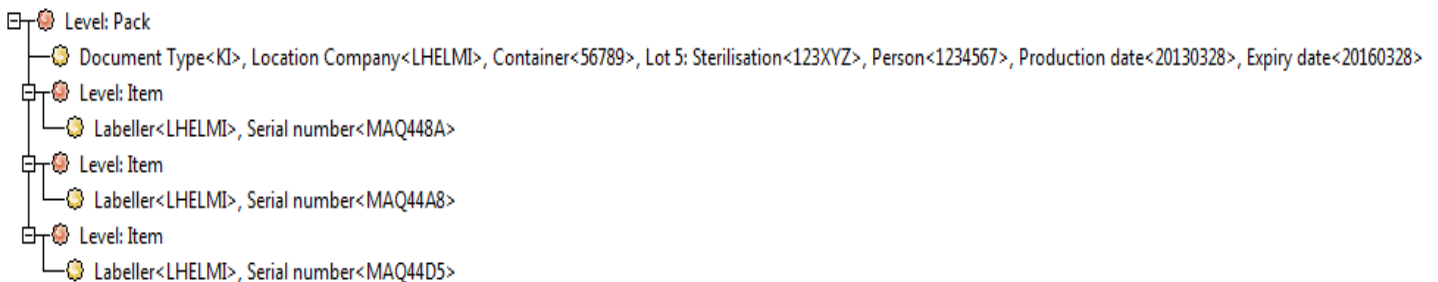


Fig. 7b) ig. 6b) Illustration Tree structure of the KIT Data Matrix content STERIETI Label (Fig. 5)

## 8 Direct marking of plates, containers, instruments

### 8.1 Steri Container plate

For labeling containers removable plates are in use marked with text, graphics and unique codes by LASER beam. For unique identification a unique Serial Number headed by a DI or type REF & Serial Number is appropriate e. g. encoded with HIBC (see table a, category A). According to the available space linear Code 128 or Data Matrix can be used. (Option with integrated RFID chip applies if RFID readers are in use).



Fig. 8) Container plate and Code 128



Fig. 9) Plate with Data Matrix & RFID with encoded HIBC

### 8.2 Name Plate for equipment, e. g. for sterilization units

Ideally the manufacturer supplies the equipment with uniquely serialized name plate and HIBC code or in DI structure. "DIN 66277 Electronic Name Plate" provides additional information for hybrid solutions with Data Matrix & RFID and for integration links to sources of equipment information via internet as optional add on features.

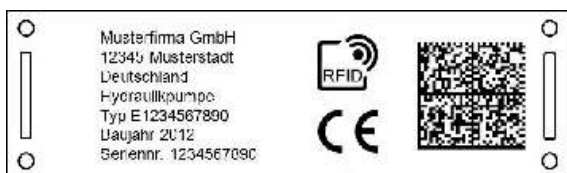


Fig. 10) E-Name Plate applied with Data Matrix & RFID, source *DIN 66277*

### 8.3 Instrument marking

For unique identification of instruments Direct Part Marking (DPM) techniques are appropriate. The most used method for applying unique Serial Numbers on surgical instruments is Laser Marking of Data Matrix. If the manufacturer does not supply instruments having been applied with Data Matrix, then the user may take use of a "LASER Service" marking even used instruments conforming to HIBC UIM or DIN 66401 Unique Identification Mark. If the square size of a Data Matrix is not efficient enough for a given surface, then the "rectangular" options of Data Matrix should be considered (see fig. 12).



Fig. 11) Unique Identification Mark - UIM as a square Data Matrix



Bild 12) UIM on a round instrument as rectangular Data Matrix

## 9 Anex Bibliography

DIN 66401 UIM – Unique Identification Mark

[www.din.de](http://www.din.de)

HIBC UIM

[www.hibc.de](http://www.hibc.de)

DIN 66277 Electronic Name Plate (2013)

[www.din.de](http://www.din.de)

HIBC Guidelines

[www.hibc.de](http://www.hibc.de)

HIBC PaperEDI

[www.hibc.de](http://www.hibc.de)

ISO 28219 Labelling and Direct Marking of Products

[www.din.de](http://www.din.de)

ISO/IEC 15418 GS1 AIs & ASC DIs

[www.din.de](http://www.din.de)

ISO/IEC 15434 Syntax for High Capacity Data Carrier

[www.din.de](http://www.din.de)

ISO/IEC 15417 Code 128

[www.din.de](http://www.din.de)

ISO/IEC 16022 Data Matrix Code

[www.din.de](http://www.din.de)

ANS HIBC 2.4 Health Industry Bar Code

[www.hibc.de](http://www.hibc.de), [www.hibcc.org](http://www.hibcc.org)

ANS MH 10.8.2 ASC Data Identifier

[info@eurodatacouncil.org](mailto:info@eurodatacouncil.org)

Joined Working Group AIDC: [www.HIBC.de](http://www.HIBC.de), [www.VDDI.de](http://www.VDDI.de)  
Hotline: phone: +49 3445 78114 0, [hotline@hibc.de](mailto:hotline@hibc.de)  
All rights reserved. © 130208oeh,; EDC, EHIBCC, VDDI e.V.