



S A F E
SERIALISATION
LABELLING
AUTOMATION

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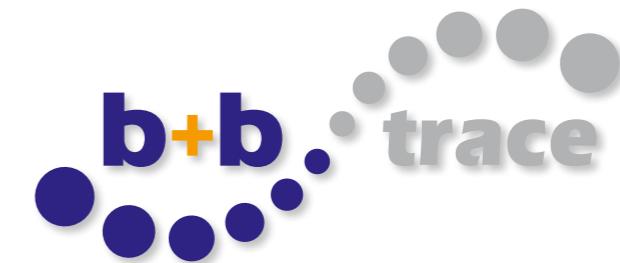
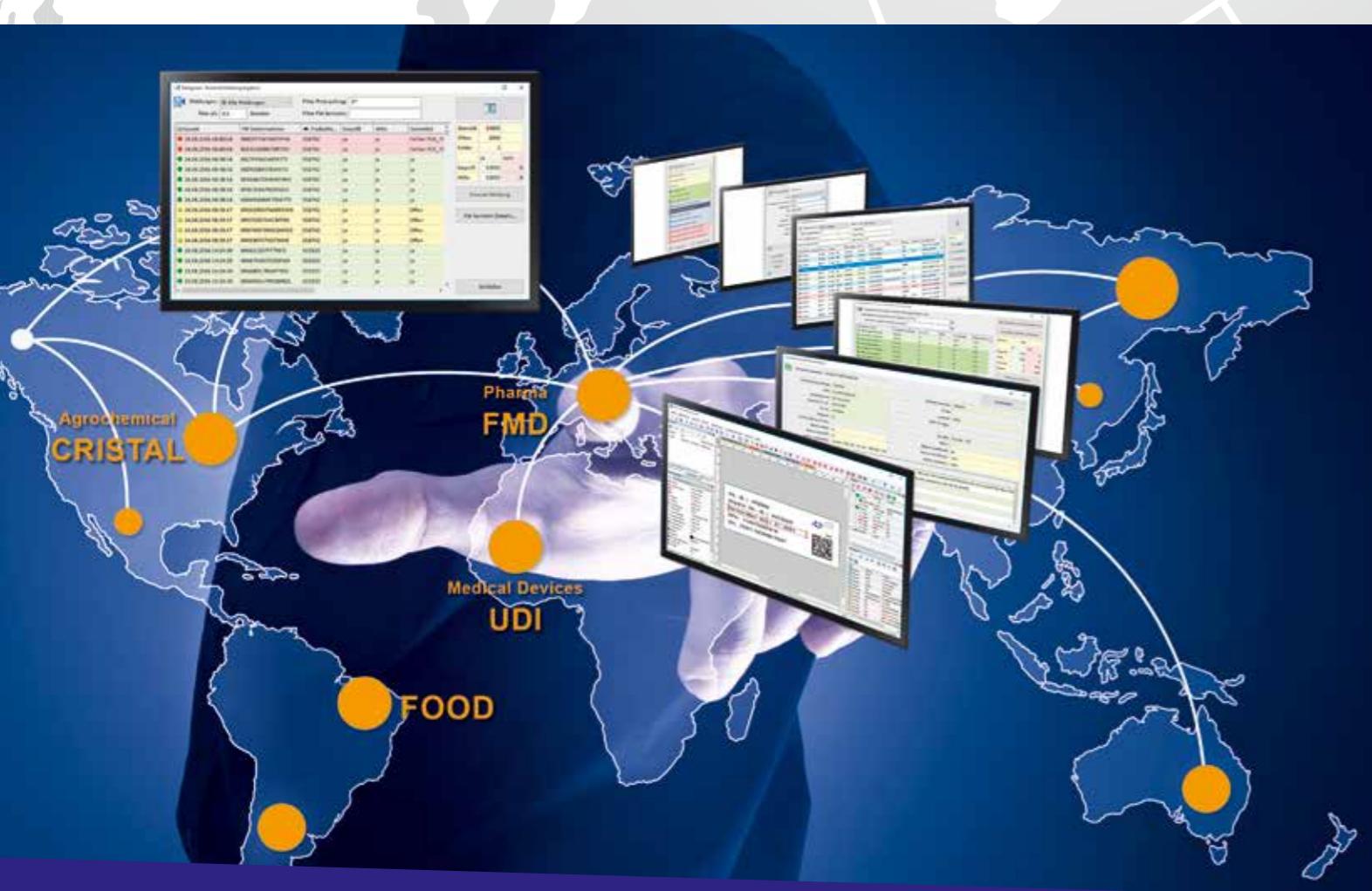
MODULAR SOFTWARE

TRACK & TRACE

for process-safe serialisation, aggregation and track and trace



SAFE SERIALISATION LABELLING AUTOMATION



To implement existing and future statutory provisions within the EU and globally, b+b Automations- und Steuerungstechnik GmbH has developed intelligent concepts for process-safe and efficient serialisation of packaging.

The central element behind these concepts is a modular software architecture that is tailored to the needs of pharmaceutical manufacturers, re-importers and contract packagers and can be adapted at any time to future requirements. These concepts are used for managing production lines or sites, adapting to new coding and aggregation requirements or expanding the equipment fleet.

The software package is also used as a platform for production management. It allows an almost unlimited number of different hardware items from various manufacturers for automation, coding and aggregation to be controlled and managed in parallel.

In addition to the formats, formulations and programs of b+b hardware components being sent automatically to the production line, equipment from other manufacturers is also parametrised for rapid product switching.

Our b+b software architecture also enables connection to the EU Hub, the international collection site for all packaging data for medicinal products. From the EU Hub, data is exchanged with national verification systems and import transactions in the medicinal product trade are balanced.

Due to the modular structure of the software architecture, the modules presented here can only represent an extract. Custom solutions or expanding existing modules with subsequent validation are possible at any point.

b+b Automations- und Steuerungstechnik GmbH has already successfully realised a wide range of major customised serialisation projects. We are happy to provide a current list of references.

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1. Serialisation

What is serialisation?

- Application of unique serial numbers to sales units / bundles / cartons / pallets
- Checking and recording of the applied data / serial numbers
- Saving, managing and forwarding / reporting of the serial numbers for subsequent track and trace

Important information about serial numbers

- Simple ascending numbers (counter) are no longer standard for serial numbers because they are easy to counterfeit. They are still only used for pallet numbers (NVE/SSCC). Instead, serial numbers now comprise random digits (0–9) and letters (A–Z), commonly with 10 to 20 places.
- To circumvent keyboard, scanner or reader issues, the letters Y, Z and O are often avoided.
- The pharmaceutical sector requires that the serial numbers are unique for a single article for several years (no duplicate numbers for any single article).
b+b trace software ensures that the serial numbers it generates are unique across all articles (no duplicate numbers, open ended).
- The chance that outside parties are able to decipher or calculate one of the generated numbers is also supposed to be at least 1:10,000.
b+b trace software ensures that this chance is 1:2 trillion for the numbers it generates.

A typical serialisation identifier for containers or packaging:

Lot: P12A63
Exp. date: 02.2021
PC: 01234567890142
SN: 1234567890ABCDEF



2. An overview of b+b trace serialisation software

bb-trace software structure

Basic software (always required):

- b+b Site Server Central server service + database
- b+b Site Manager Management software / order preparation

Pharmaceutical software modules:

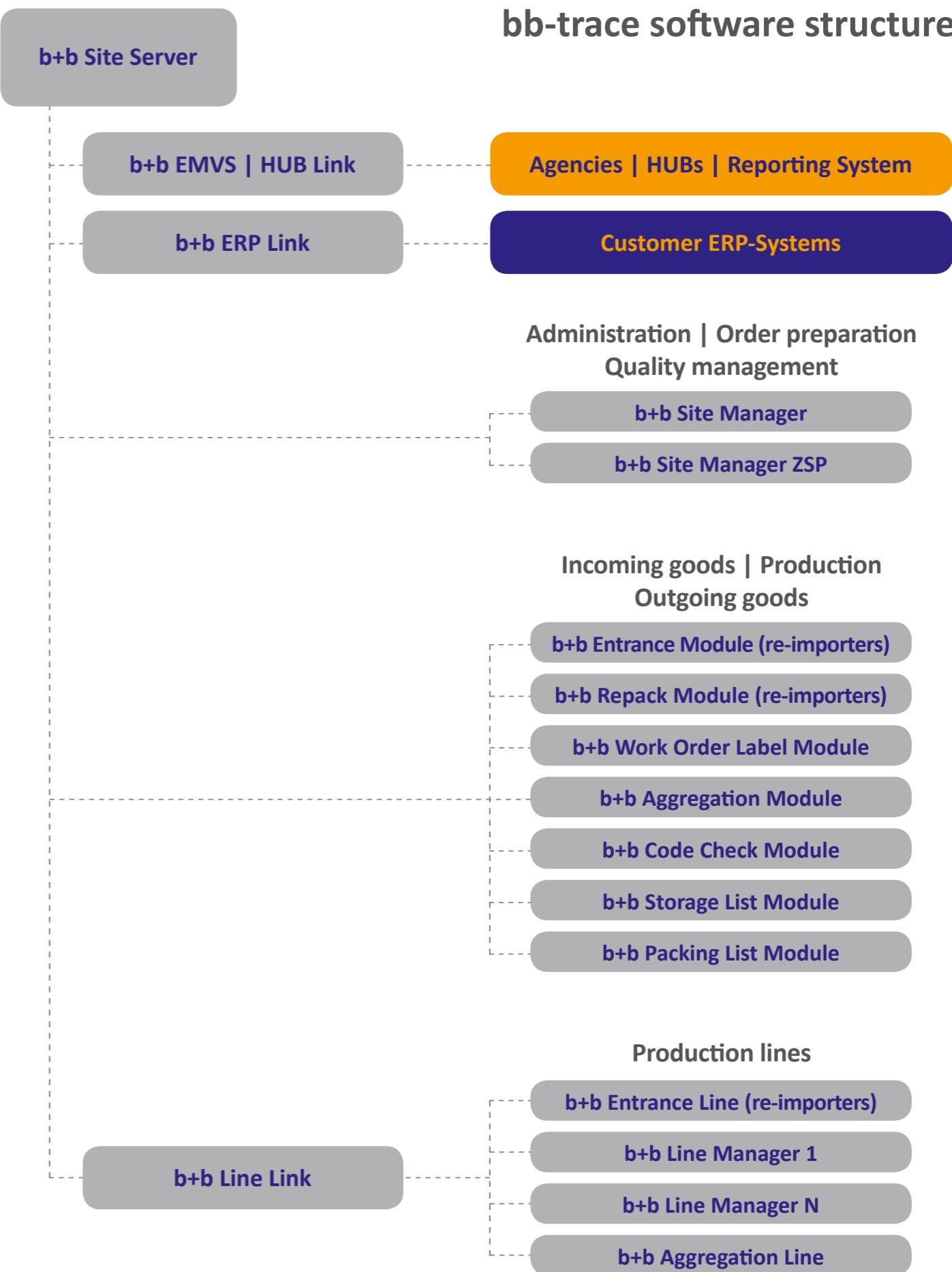
- b+b Work Order Label module Production software: rapid order creation + printing of serialised product labels (LP4)
- b+b Code Check Module Production software: manual checking / recording of printed product labels per scanner
- b+b Storage List Module Production software: manual distribution of inspected product labels to storage location via scanner
- b+b Packing List Module Production software: recording of product labels in dispatch (during the preparation of shipping crates), printing of pack lists
- b+b EU-HUB Bridge Module Gateway for automated access to the EMVS (European Medicines Verification System)

Pharmaceutical re-importer software modules:

- b+b Entrance Module Production software (re-importers): manual incoming goods receipt, recording using handheld scanners
- b+b Repack Module Production software (re-importers): assigning incoming goods to work orders and decommissioning via HUB system

System modules:

- b+b Line Manager System software: Printing and checking (or just checking) of serialised product labels (compatible b+b hardware: LSS, LSS-V, HSF)
- b+b Entrance Line Module System software (re-importers): automated incoming goods receipt, recording and sorting (e.g. b+b sorting system)
- b+b Aggregation Label Module System software: Printing, checking and aggregation of product, bundles, cartons and pallet labels (LP4)



3. b+b trace serialisation software – Packages

b+b trace serialisation software is made up of various modules. Not every customer requires every module. The individual modules are configured as required by b+b depending on their purpose.

Below are some typical software packages that can be supplemented or modified in accordance with customer requirements:

The packages **BASIC / STANDARD / RE-IMPORTER** are used for the standard pharmaceutical market.

This market only requires serialisation of the basic products (product box or packaging of the sales unit) with no serialisation of bundles, cartons or pallets. There is no aggregation. From case to case, products are also allocated a warehouse or dispatch number during storage or shipping .

Order management for the pharmaceutical sector is therefore very easily carried out in b+b Site Manager. Every order contains only a single batch and manages only the serial numbers of the sales units. In contrast, the reporting/decommissioning/verification of serial numbers to superior authority systems is very comprehensive because the pharmaceutical sector maintains a transnational management network.

The „**AGGREGATION**“ package is aimed at the agrochemical industry or all sectors that require complete serialisation at all aggregation levels (individual products/bundles/cartons/pallets).

Article and order management within b+b Site Manager has a more complex structure in this case. The article data must include how many sub-units are included in the higher level stacks, cartons and pallets. Weight data, different GTIN article numbers (per aggregation level) and additional text are also required.

The orders no longer have to be made up of a single batch. Several batches can be included in an order and of course containers from different batches can be packed together in a carton or on a pallet. b+b Site Server generates/imports/manages separate serial numbers for each aggregation level of an order. The full serial number hierarchy of the numbers tested as ‘good’ can be reported to a superior system (e.g. SAP).

4. b+b trace serialisation software – BASIC package

The basic package for contract manufacturers and folding box manufactures in the pharmaceutical sector:

- Simple creation of orders and their serial numbers
- Printing and checking in the system
- Forwarding numbers to clients

BASIC modules: b+b Site Server

b+b Site Manager

b+b Line Manager (for use in b+b systems)

- With the basic package, new serialisation orders for products can be created very rapidly using Site Manager
- In a b+b system (e.g. HSF for folding boxes or LSS for finished products), the orders are processed (printed and checked)
- Using Site Manager, the checked numbers can be exported for forwarding to clients
- No article management, no reporting processes to authorities, no aggregation



5. b+b trace serialisation software – STANDARD package

The standard package for manufacturers of pharmaceutical products:

- Creating orders and their serial numbers
- Printing and checking in the system or manually
- Storage documentation (optional)
- Shipping documentation (optional)
- Reporting numbers to authority systems

STANDARD modules:

- b+b Site Server
- b+b Site Manager
- b+b Work Order Label Module
- b+b Code Check Module
- b+b Storage List Module
- b+b Packing List Module
- b+b Line Manager (for use in b+b systems)
- b+b EU-HUB Bridge Module

- In addition to the features of the basic package, the b+b Site Server interface to the German pharmaceutical reporting system (SecurPharm) is also included.
b+b Site Manager provides additional operating windows for reporting, checking and decommissioning numbers for this purpose.
- Optional: Interface to the EU reporting system
(b+b Site Manager article management is then mandatory)
- For printing serialisation labels in advance:
b+b Work Order Label Module (+ LP4 licence)
- For checking printed labels: b+b LSS-V system (includes b+b Line Manager on HMI) or manual checks using the b+b Code Check Module
- For direct printing and checking of products:
b+b LSS system (includes b+b Line Manager on HMI)
- For direct printing and checking of product folding boxes:
b+b HSF system (includes b+b Line Manager on HMI)

6. b+b trace serialisation software – RE-IMPORTER package

The full package for pharmaceutical re-importers enables:

- Recording and checking of purchased 'raw materials'
- Creating 'finished goods' orders and their serial numbers
- Printing and checking in the system or manually
- Shipping documentation
- Reporting numbers to authority systems

RE-IMPORTER modules:

- b+b Site Server
- b+b Site Manager
- b+b Entrance Module
- b+b Work Order Label Module
- b+b Code Check Module
- b+b Storage List Module
- b+b Packing List Module
- b+b Entrance Line Manager (for use in b+b sorting systems)
- b+b Repack Module
- b+b Line Manager (for use in b+b systems)
- b+b EU-HUB Bridge Module

- The raw materials purchased by the re-importer are either manually recorded using b+b Entrance Module or automatically by the b+b Entrance Line Module on a sorting system.
- In addition to the standard package, b+b Site Manager provides additional operating windows for managing raw materials
- With an EU Hub connection: automatic query to verify the purchased raw materials. The results are shown in the Site Manager
- b+b Repack Module Production software (re-importers): Assigning incoming goods to work orders and decommissioning via HUB system
- Also in b+b Site Manager:
Marrying of 'raw materials' with 'finished goods' for serialisation orders
- For the finished goods (repackaged raw materials or in-house produced goods) the same modules are available to the re-importer as for a pharmaceutical manufacturer (STANDARD package)

7. b+b trace serialisation software – AGGREGATION package

The serialisation package for the agrochemical industry and all other sectors that require serialised identification at all aggregation levels:

- Creating/importing article master data and orders (not from a single batch) and their serial numbers at all aggregation levels
- Printing and checking in automated production lines or on manual workbenches
- Transferring the serial number hierarchy to the clients

AGGREGATION modules:

b+b Site Server

b+b Site Manager (expanded order/article management)

b+b Aggregation Label Module (production)

- Due to the different order and article management, only b+b Site Server and the underlying management functions of b+b Site Manager are identical to the other packages.
The existing pharmaceutical modules (Work Order, Entrance, Packing List and Code Check modules) are not available!
- The normal Line Manager for b+b systems (HSF/LSS) is also not compatible!
Aggregation Label Module is the substitute in production.
- The b+b Aggregation Label Module is very flexible in its use. It can control both individual line stations as well as reprinting stations and manual work stations. It prints and controls labels at all aggregation levels and in doing so communicates with control systems and checkweighers.
There is a comprehensive range of reworking and printer control functions available (foundation: LP4).



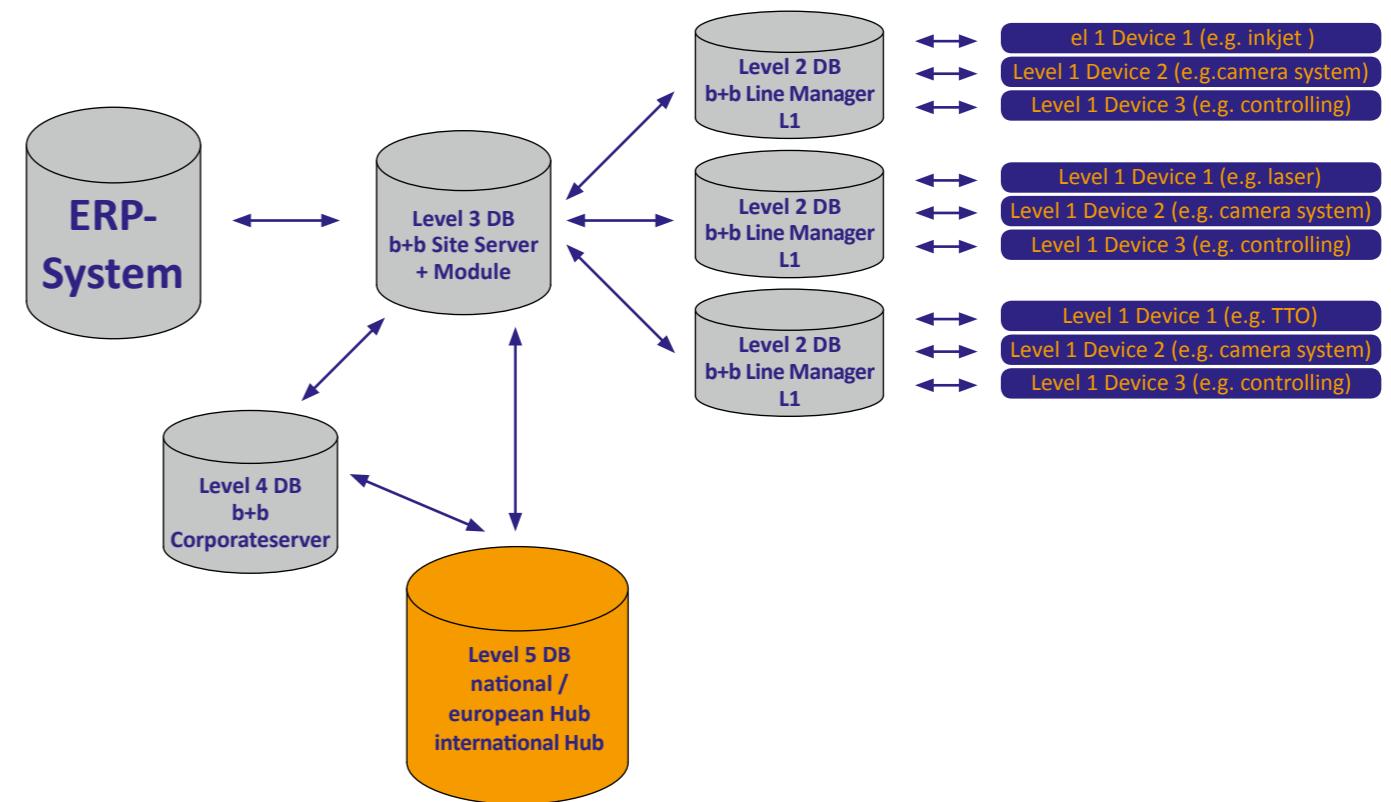
STS – semi-automatic aggregation of folding boxes

8.1 b+b trace serialisation software – Details about the modules

8.1 b+b Site Manager

Basic software (always required)

- Control centre for the entire software module (Windows service on the server in the network)
- Data storage in a Microsoft SQL Server database (minimum: SQL Server 2008 R2, recommended: SQL Server 2014)
- Connects to and exchanges data with customer systems (ERP, inventory management, warehouse management, etc.)
- Connects to and exchanges data via the internet with authorities or reporting bodies (e.g. with the German SecurPharm system)
- Optional: Connects to the pharmaceutical EU Hub system (b+b SOAP EMVS Gateway module)
- Connects to and exchange with production lines in the customer network
- Manages all master data, article data and order data required for serialisation
- Generates/imports unique serial numbers for the orders



8.2 b+b Site Manager

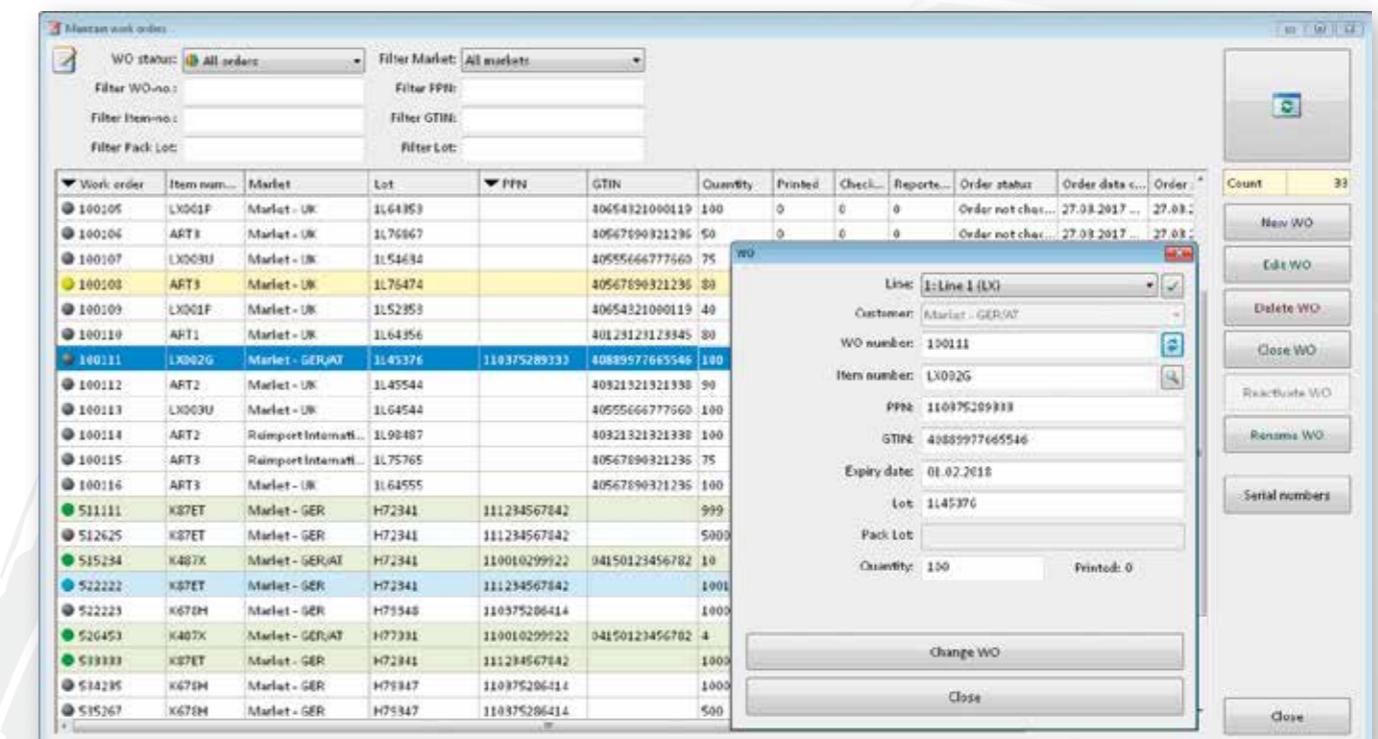
Basic software (always required)

Central management software for the data contained in the b+b Site Server database.

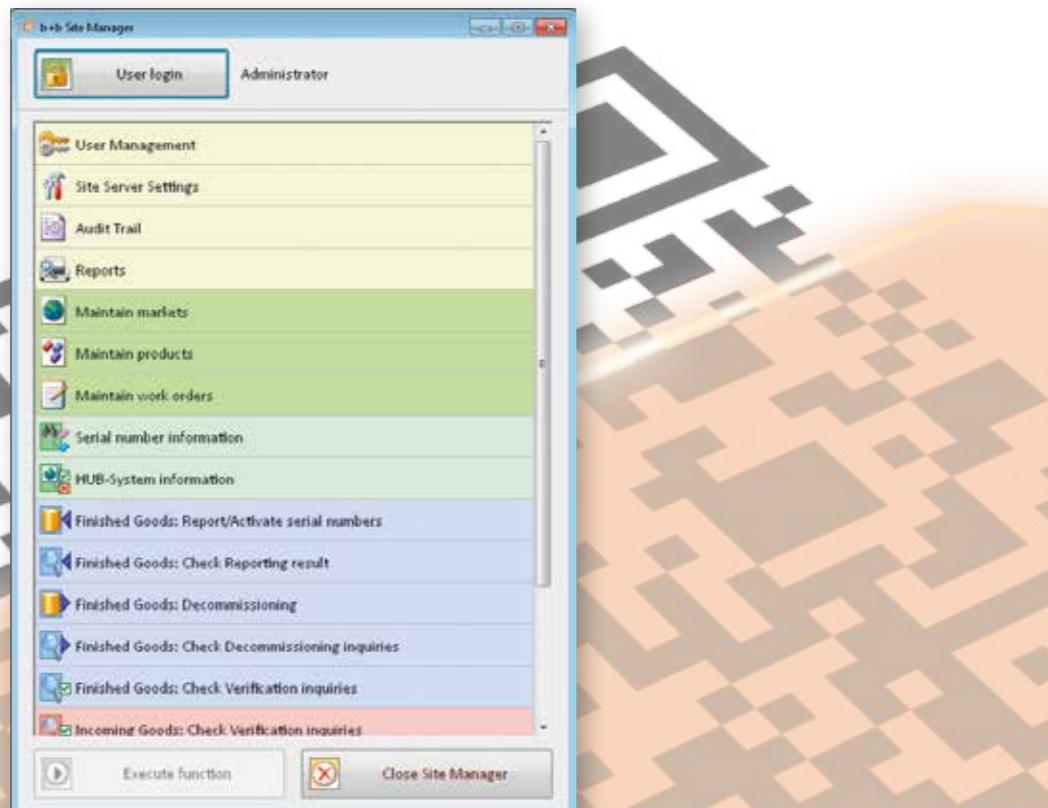
It can be used on any Windows PC in the network without being installed and enables:

- Management of own users / user groups
- Management of Site Server settings
- Management of the audit trail (21 CFR Part 11)
- Management of reports / report printing
- Management of customer and reporting master data
- Management of product data
- Management of orders (creation, change, line allocation)
- Management of reports / export of serial numbers
- Decommissioning of serial numbers (in case of loss, theft, destruction, ...)
- Verification of serial numbers (queries to the reporting systems)

b+b Site Manager: Pharmaceutical order management



b+b Site Manager: Main user interface



b+b Site Manager: Checking the report outcomes

Time stamp	FG serial number	Work order	Checked	Active	Reported
28.03.2017 13:39:26	01CWFKCLLHFORT...	558487	Yes	Yes	Open
28.03.2017 13:39:26	03TRKFOO6MULR...	558487	Yes	Yes	Open
24.08.2016 08:40:04	0RK0P7VTRJUE9846	558742	Yes	Yes	Error: PUS_TE_TX_02 - Mit de...
24.08.2016 08:40:04	0JLBIV8XBFR790	558742	Yes	Yes	Error: PUS_TE_TX_02 - Mit de...
24.08.2016 08:39:17	091EIR97WARF6...	558742	Yes	Yes	Open
24.08.2016 08:39:17	0R97EXD74ACBFP9X	558742	Yes	Yes	Open
24.08.2016 08:39:17	0R97MEFIR61QW...	558742	Yes	Yes	Open
24.08.2016 08:39:17	0R9E8EFF7NDT9KHE	558742	Yes	Yes	Open
24.08.2016 08:38:54	032TFWWIAXSR7TF	558742	Yes	Yes	Yes
24.08.2016 08:38:54	0BD5C84FEN39R7U	558742	Yes	Yes	Yes
24.08.2016 08:38:54	02BA857OMUFRE9...	558742	Yes	Yes	Yes
24.08.2016 08:38:54	0F9E3E0A7H1RF65U	558742	Yes	Yes	Yes
24.08.2016 08:38:54	0IKWFM44ME759R7...	558742	Yes	Yes	Yes
23.08.2016 14:24:30	09661C57177997J	533333	Yes	Yes	Yes
23.08.2016 14:24:30	09667D57E250FWA	533333	Yes	Yes	Yes
23.08.2016 14:24:30	09668BL7848FTMD	533333	Yes	Yes	Yes
23.08.2016 14:24:30	0966FB5U7P00MN...	533333	Yes	Yes	Yes
23.08.2016 14:24:30	0966FOC570NALU...	533333	Yes	Yes	Yes
23.08.2016 14:24:30	09676LO05K8TFWL...	533333	Yes	Yes	Yes
23.08.2016 14:24:30	09676PF559GDTT	533333	Yes	Yes	Yes

8.3 b+b Work Order Label Module

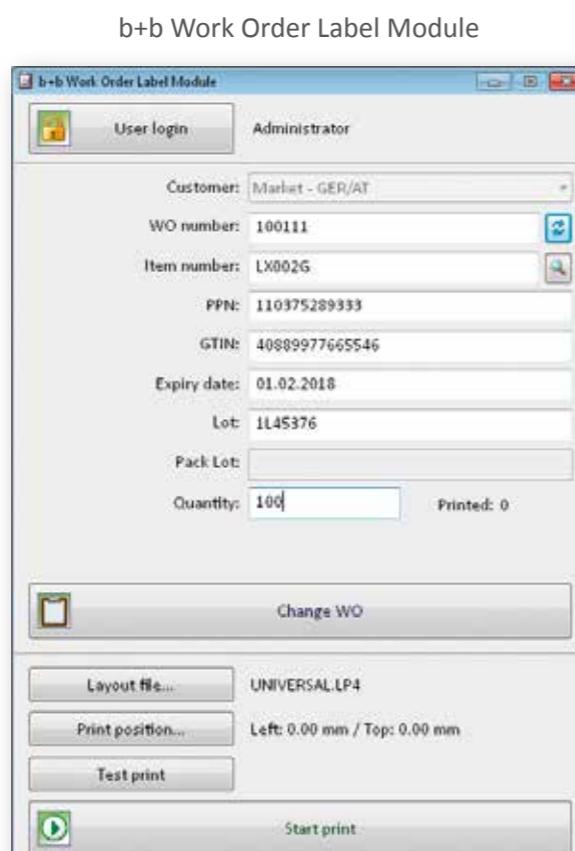
Additional modules (pharmaceutical)

Software to rapidly generate pharmaceutical serialisation orders in production. The following pharmaceutical-specific data must be entered or recorded by a handheld scanner.

- Order number
- Article number (German PPN and/or international GTIN)
- Batch number (LOT)
- Expiry date (EXP)
- Order size (number of serial numbers)
- Optional: internal batch number, internal article number, customer number

The b+b Work Order Label Module automatically generates or imports the serial numbers required for the order.

- Optional: immediate printing of the serialised product labels on a TTF printer (foundation: LP4)
- Optional: Generating the printing request for other printing systems



8.4 b+b Code Check Module

Additional modules (pharmaceutical)

Software to record/check serialised product labels using handheld scanners.

- Transfers the recorded numbers + test results to the b+b Site Server (database)
- Only 'good' tested products can be registered on Hub systems

b+b Code Check Module - Order selection

Work order	Item number	Pack Lot	Lot	PPN	GTIN	Format 1	Order status
100108	ART3		1L76474		40567890321...	GTIN	Order active, I
100109	LX001P		1L52353		40654321000...	GTIN	Order not che
100110	ART1		1L64356		40123123123...	GTIN	Order not che
100111	LX002G		1L45376	110375289333	40889977665...	UNIVERSAL	Order not che
100112	ART2		1L45544		40321321321...	GTIN	Order not che
100113	LX003U		1L64544		4055666777...	GTIN	Order not che
100114	ART2	1L47567	1L98487		40321321321...	RI-GTIN	Order not che
100115	ART3	1L74567	1L75765		40567890321...	GTIN_UK	Order not che
100116	ART3		1L64555		40567890321...	GTIN	Order not che
S12625	K87ET	S612A42	H72341	111234567842		PPN	Order not che
522222	K87ET	6556A63	H72341	111234567842		PPN	Order parked

b+b Code Check Module – Recording of serial numbers

Work order: 522222
Item number: K87ET
Pack Lot: 6556A63
Count: 30

Check for correctness:
 Check for errors:

JVH1K32R7GWE1QON
31QX74LJ15VCHGV2
JGRHELNV60H1B121
OSGH07V1QE4J0LP
SQ1JH6E1VLJUH680
RTO4FJFM1VPOH19K
BWMQBFFC11JXVODT
1HVS31D0CNQMAX2
ONQDBAH11VDHPQ4
1ONIHGE1VVGKLQIK

Cancel Finish

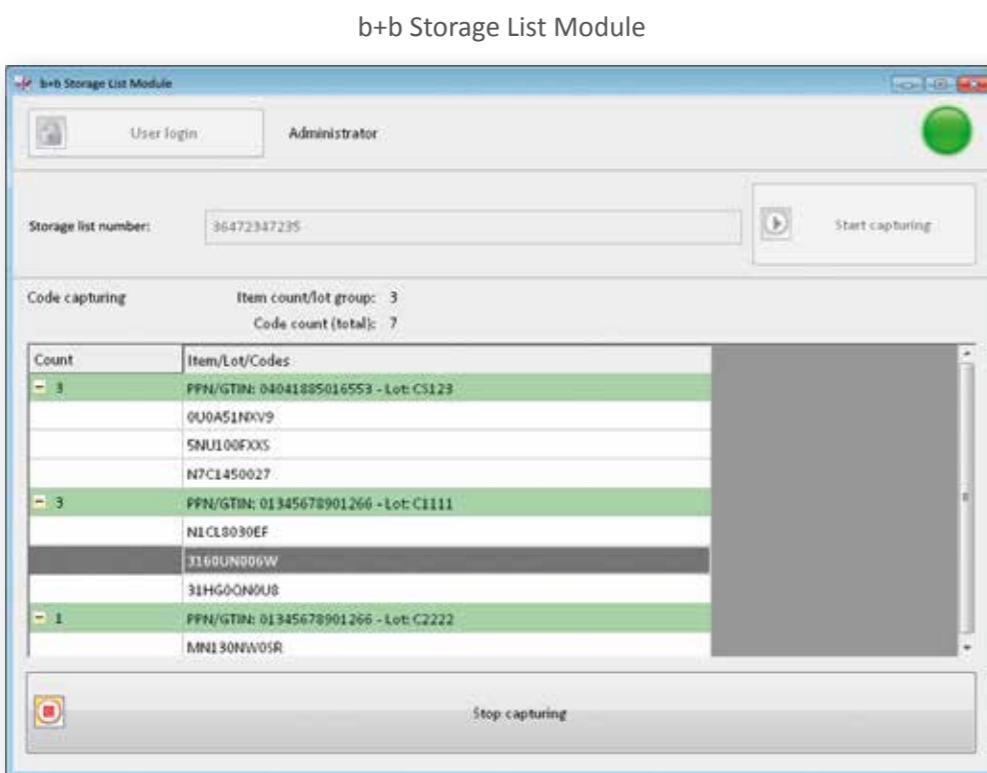
8.5 b+b Storage List Module

Additional modules (pharmaceutical)

Optional software for production:

- Assigns serialised products by handheld scanner to a warehouse list / pallet number (simple aggregation for internal warehouse management)
- Transfers the recorded numbers and the assigned warehouse list to the b+b Site Server (database)
- Prints the warehouse list / pallet label on a Windows printer

b+b Storage List Module



Count	Item/Lot/Codes
- 3	PPN/GTIN: 04041885016553 - Lot: C123 000A51NXV9 SNUL100FXXS N7CL450027
- 3	PPN/GTIN: 01345678901266 - Lot: C1111 N1CL8030EF 3160UN006W 31HG0ON0U8
+ 1	PPN/GTIN: 01345678901266 - Lot: C2222 MN130NW0SR

User login Administrator Start capturing

8.6 b+b Packing List Module

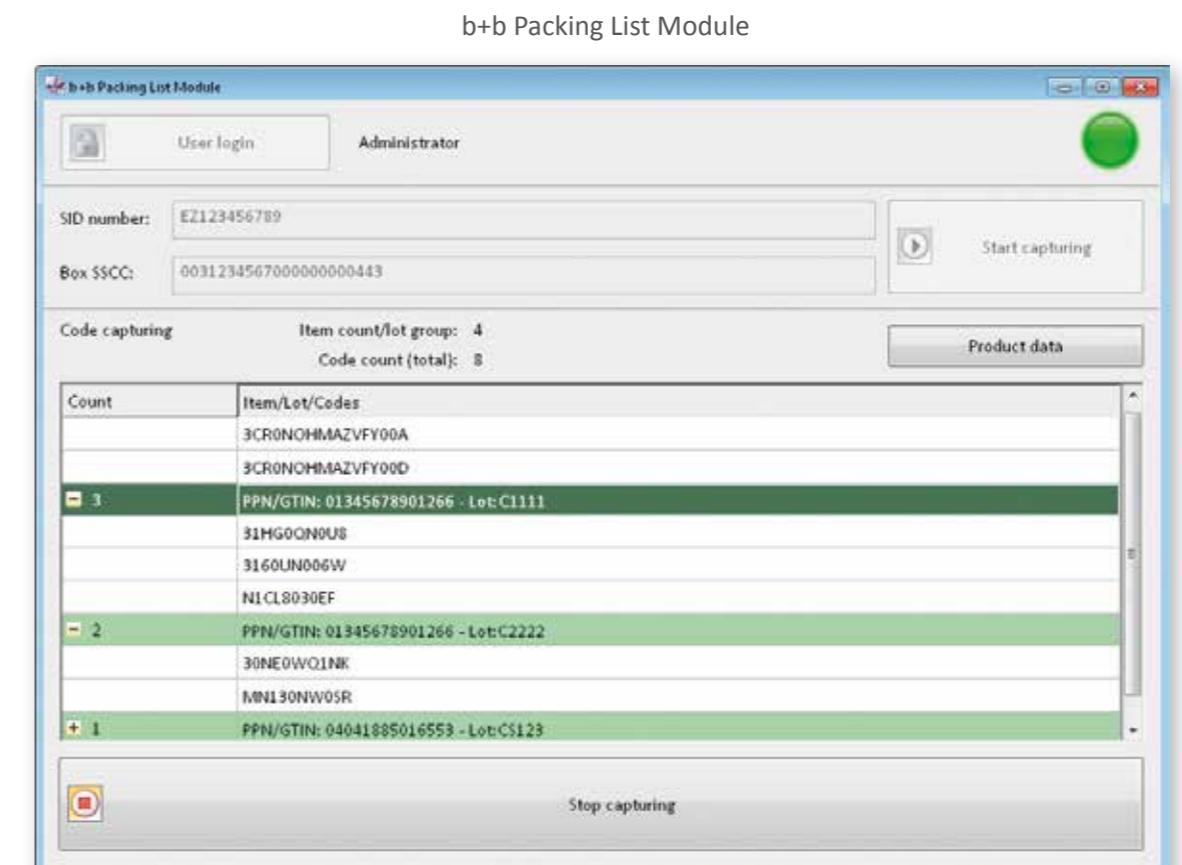
Additional modules (pharmaceutical)

Software for shipping:

Records serialised product labels by handheld scanner during packaging.

- Transfers the recorded numbers and the shipping number to the b+b Site Server (database)
- Prints the packing list on a Windows printer

b+b Packing List Module



Count	Item/Lot/Codes
- 3	3CR0NOHMAZVFY00A 3CR0NOHMAZVFY00D
- 2	PPN/GTIN: 01345678901266 - Lot: C1111 31HG0ON0U8 3160UN006W
+ 1	PPN/GTIN: 01345678901266 - Lot: C2222 30NE0WQ1NK MN130NW0SR
+ 1	PPN/GTIN: 04041885016553 - Lot: C123

User login Administrator Start capturing Product data Stop capturing

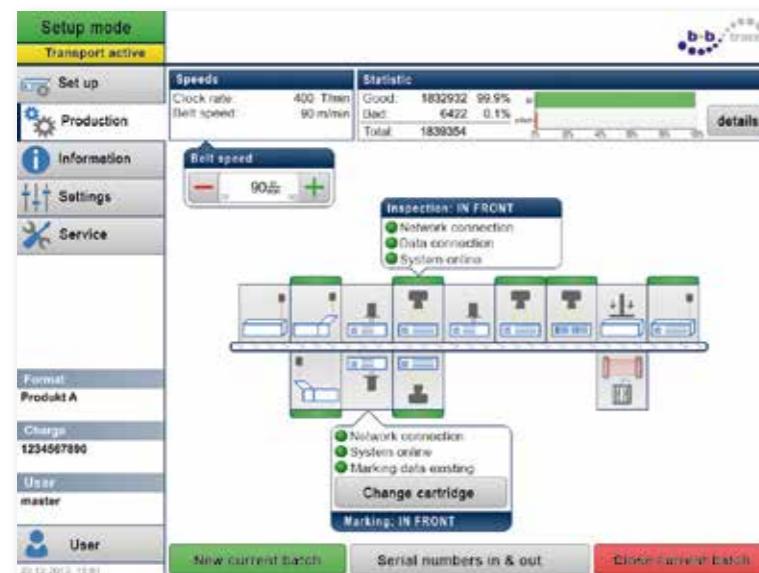
8.7 b+b Line Manager

Additional modules (pharmaceutical)

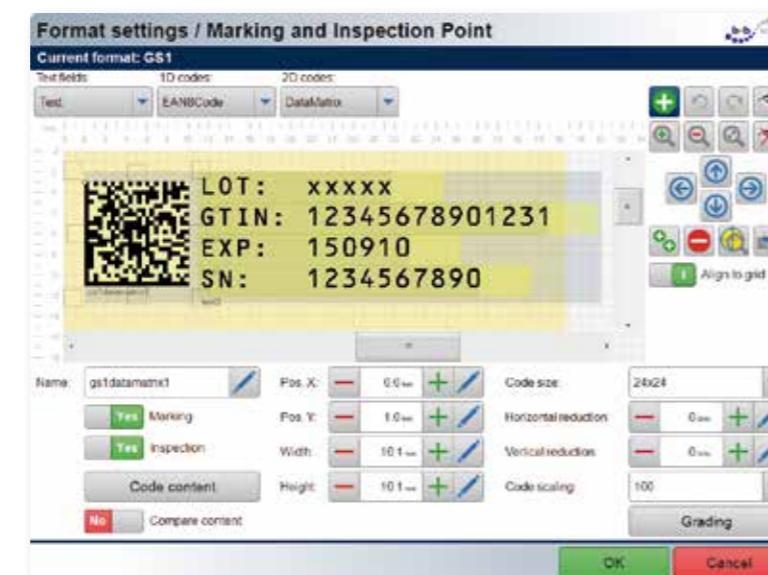
For the HMI system PC

(for example, HSF for folding boxes or LSS or LSS-V for finished products).

- Order selection (list with production orders from the b+b Site Server)
- Prints via an inkjet system
- Checks with a Cognex camera
- Deactivates incorrect codes with a handheld scanner
- Special feature: b+b Line Manager software has an integrated format editor for printed image
- Transfers the recorded numbers and the test result to the b+b Site Server (database)



b+b Line Manager (HMI software)

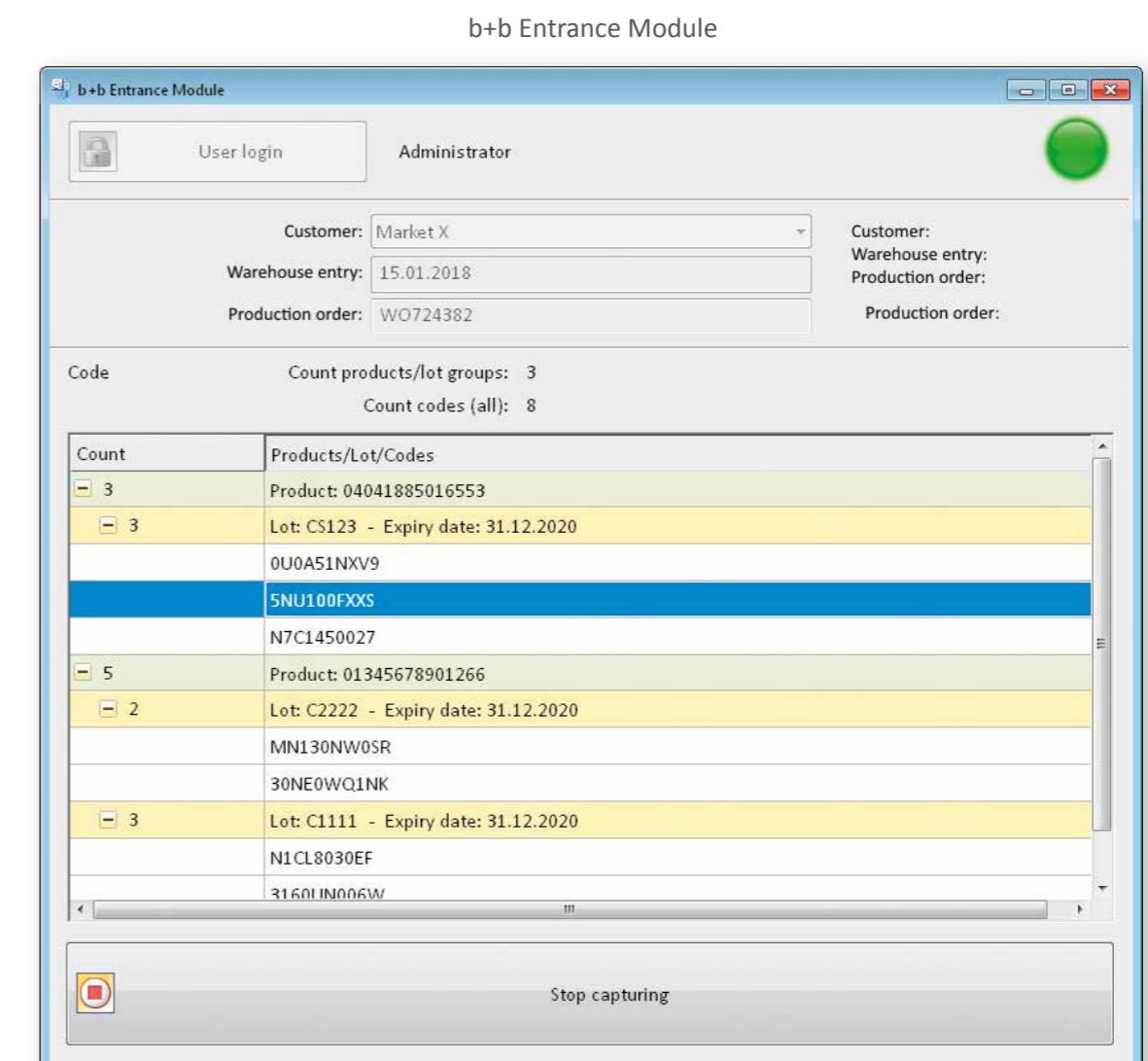


8.8 b+b Entrance Module

Additional modules (pharmaceutical re-importer)

Software for incoming goods:

- Manually records raw materials by handheld scanner, automatically allocates to the warehouse location, prints the warehouse label
- Transfers the recorded numbers and the warehouse location to the b+b Site Server (database)
- Optional: automatic verification query to the EU reporting system

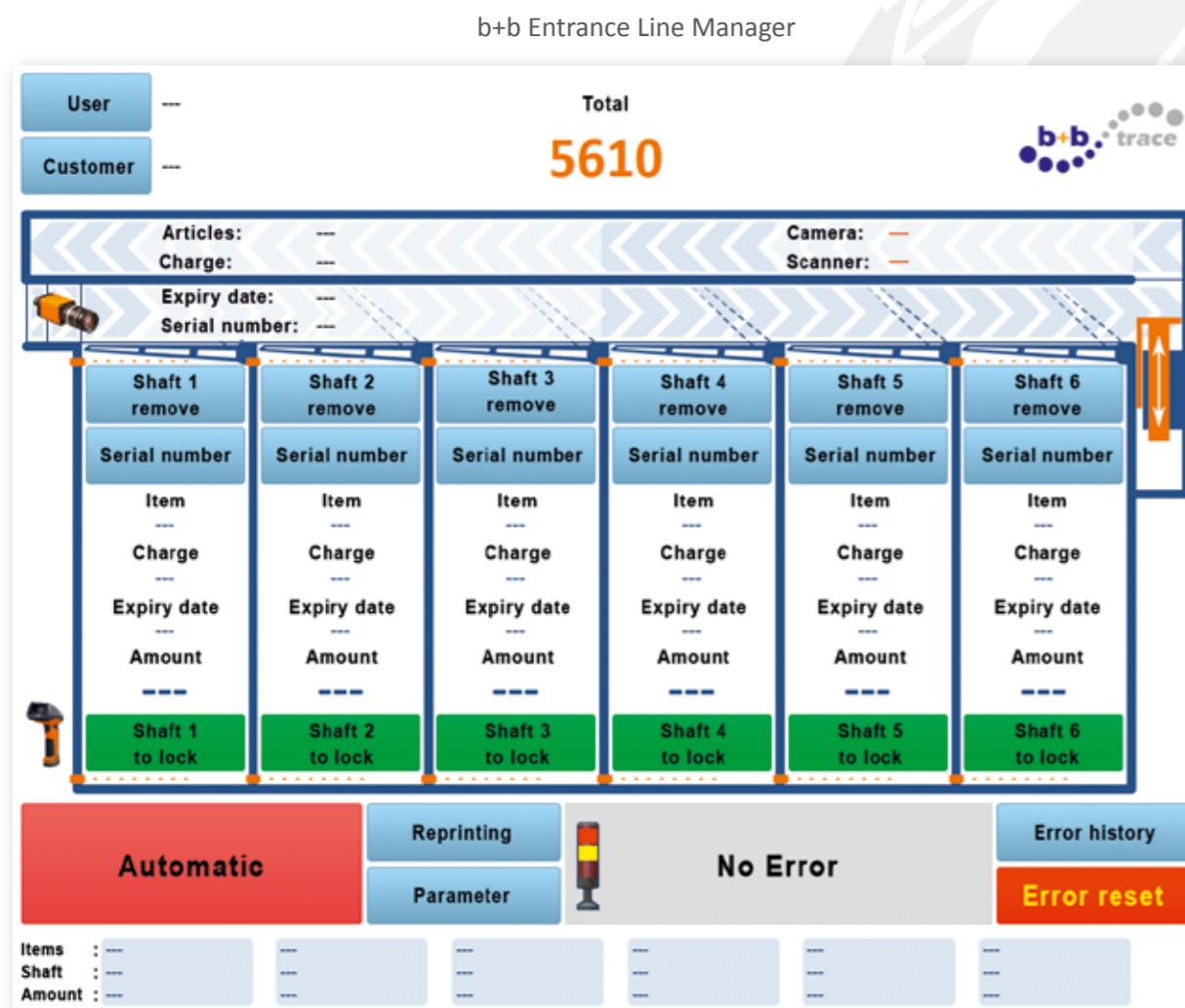


8.9 b+b Entrance Line Manager

Additional modules (pharmaceutical re-importer)

b+b Line software for HMI system PC (for example, on a b+b sorting system).

- Records incoming raw materials with a high-performance camera
- Automatically sorts in the system (sorted belt outward transfer)
- Returns raw materials that are not recorded / cannot be sorted
- Prints warehouse label
- Optional: automatic verification query to the EU reporting system



8.10 b+b Repack Module

Additional modules (pharmaceutical re-importer)

For the automated message on the EU Hub.

Process description:

b+b Repack Module: Products defined as „repacked“ are automatically reported to the EU Hub. This process can be triggered both by an automatic product sorting system and by hand-held scanner. The software is directly connected to the central management software of the b + b Site Server database. Depending on the authorization, the logged in user can start and use the corresponding administration masks.

The software is also centrally usable, e.g. in a network drive. After starting the program, the software will occupy a license on the b+b Site Server, and upon completion, the license will be released.

8.11 b+b EU-HUB Bridge Module

For automated access to the EMVS Hub (EMVS = European Medicines Verification System) via the b+b Site Server.

For managing serial numbers the following actions are possible:

- Reports and decommissions serial numbers of in-house products
- Reverses the decommissioning of in-house products
- Rewards – decommissions serial numbers from third-party products (re-importer)
Note: In the EU Hub, only serial numbers for in-house articles can be registered or decommissioned.
Serial numbers of third-party articles can only be marked as ‘repacked’.
- Verifies serial numbers
- Reports and maintains article master data in the EU Hub

Process description:

The b+b EU-HUB Bridge Module operates as a secure connection between the customer's internet server and the EU-HUB server (b+b can provide optionally an internet server as a fee-based service).

The Bridge Module transfers all the required information from the b+b Site Server service to the EU-HUB by using the SOAP protocol, and also manages the asynchronous reply messages from the EU-HUB.

The messages will be transferred to the b+b Site Server, and stored in the local database.

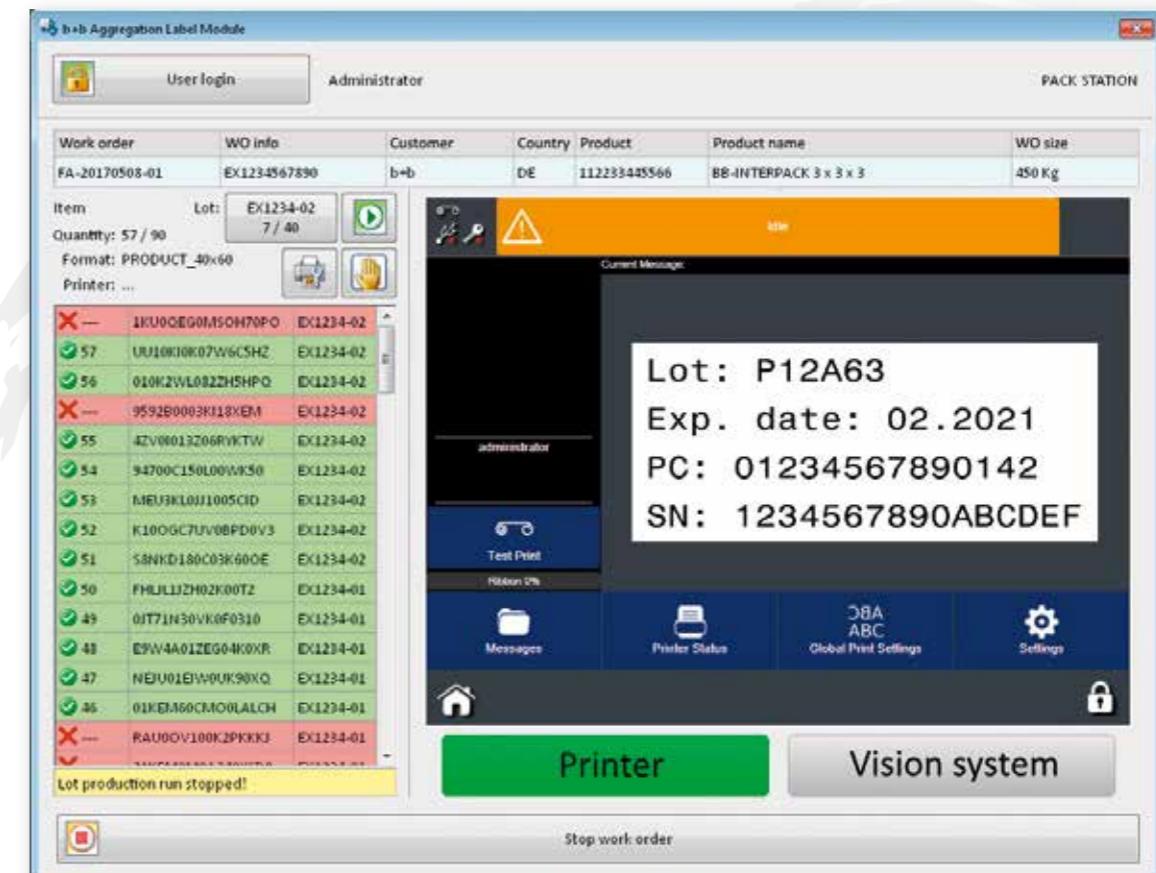
8.12 b+b Aggregation Label Module

Additional modules (aggregation)

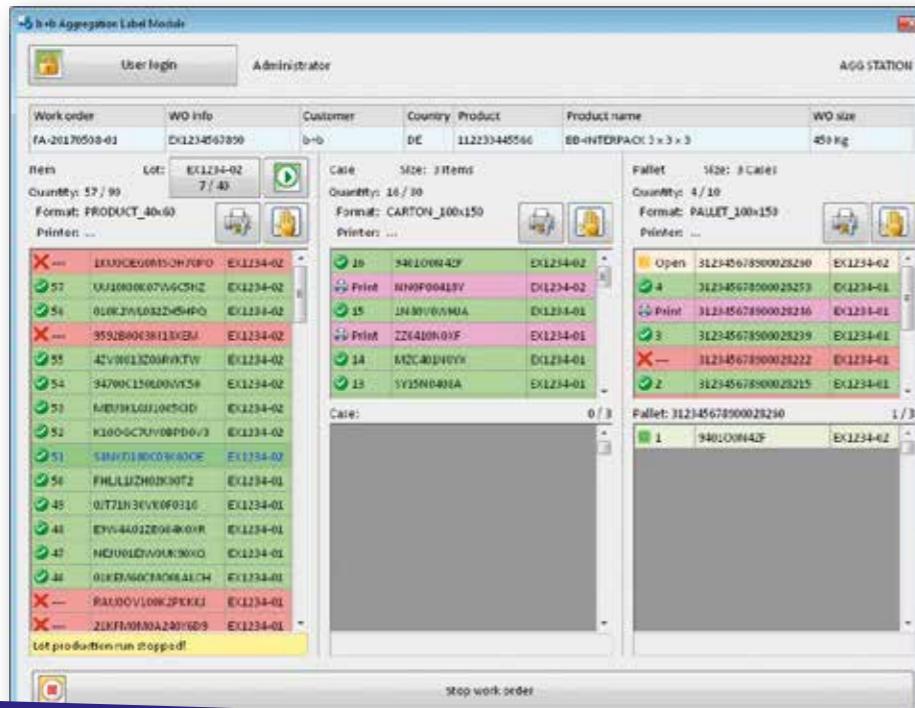
Flexibly configured production software for printing and checking serialisation labels at all aggregation levels. Ideal for integrating printing and checking stations for serialisation tasks into existing production lines.

- Printing via LP4 engine, for higher aggregation levels all LP4 TTF printer types are optional (CAB recommended), for primary products: printing via CAB or Domino-V
- Checking with Cognex cameras or Cognex Dataman / handheld scanner
- Comprehensive rework functions via handheld scanner
- At manual workstations: parallel coverage of several aggregation levels, e.g. on a common workbench for cartons and pallets
- On line HMIs: Control of production control systems (IPZ/Siemens SPS) with integrated FIAVis HMI surface
- On line HMIs: Linkage of 'n' HMI stations, for example
 1. HMI for order start and primary products
 2. HMI for carton station
 3. HMI for pallet station
- Sends article weight to the checkweigher
- Transfers the entire number hierarchy + test result to the b+b Site Server (database)

b+b Aggregation Label Module – line HMI (containers)



b+b Aggregation Label Module – manual workbench for cartons and pallets



LSS - semi-automated serialisation module

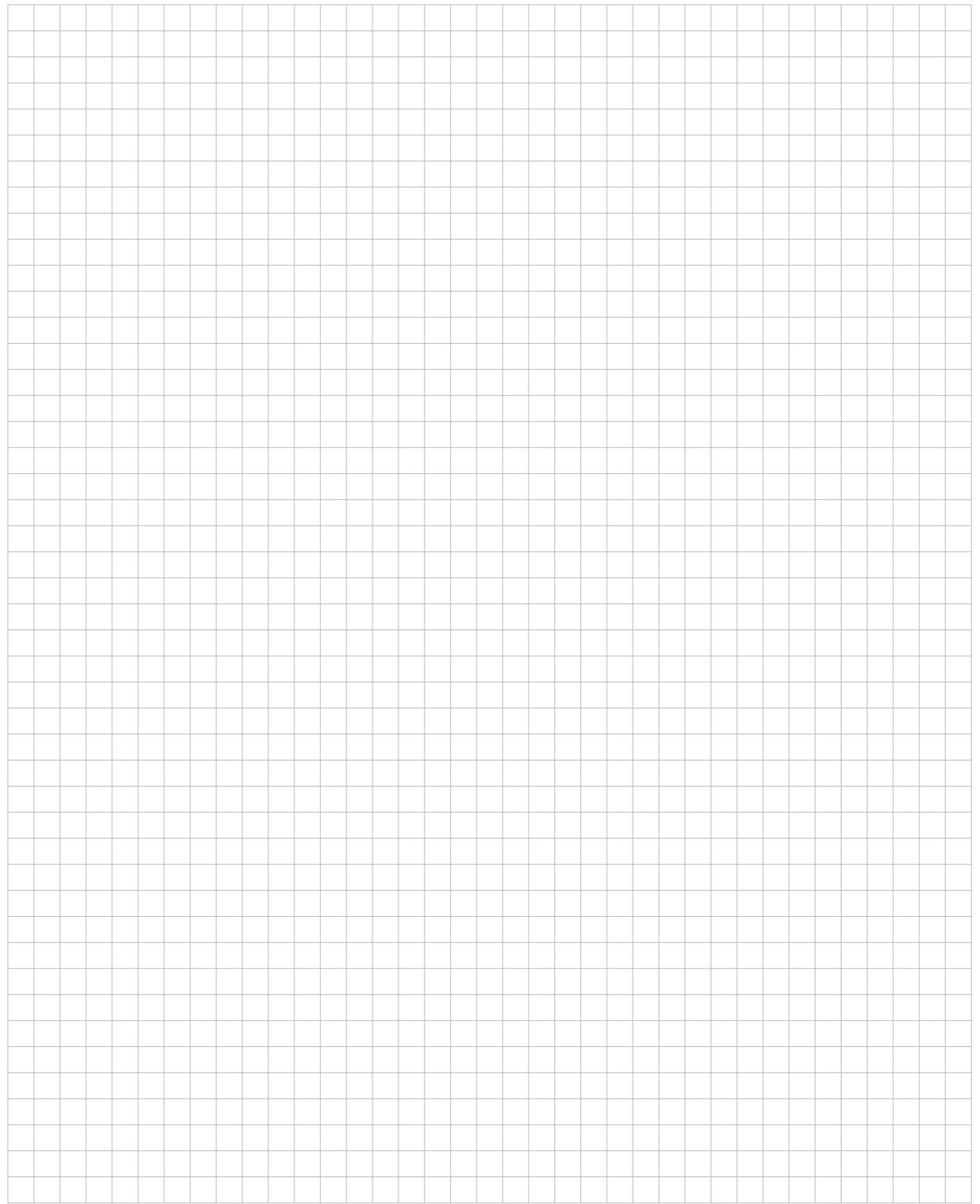


SAFE

SERIALISATION LABELLING AUTOMATION



notice



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