



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Opportunities and Challenges in the Application of UDI

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Shandong Weigao Group



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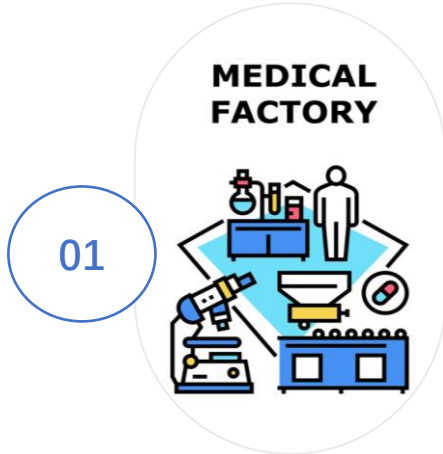
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Opportunities for manufacturers

PART. 01

Significance of applying UDI for manufacturers



Facilitating industrial upgrading

As playing the primary role in the application of UDI, manufacturers can improve the IT application level of product manufacturing through the establishment of the UDI system. As a medium, UDI enables manufacturers to strengthen the combination of hardware and software and enhance the production efficiency and management.



Enhancing quality monitoring and improvement

UDI can strengthen the monitoring of adverse events, assure the accurate recall of products with quality problems, optimize the product quality management system, reduce the risk and cost of compliance operation, empower the management of manufacturers, and promote the high-quality development of the medical device industry.



UDI System applied by Weigao Group

Since the manufacturing operation management platform was established, Weigao group has integrated its **UDI database**, **UDI coding system** and **UDI traceability system**. This establishment enables the information sharing across various systems and departments, the efficient combination of hardware and software, and the whole-process control during production, which improves the fine management level of medical device production. Weigao Group is continuously optimizing the functions of its UDI system in accordance with the needs of production management, quality control, logistics tracking, and regulatory supervision.



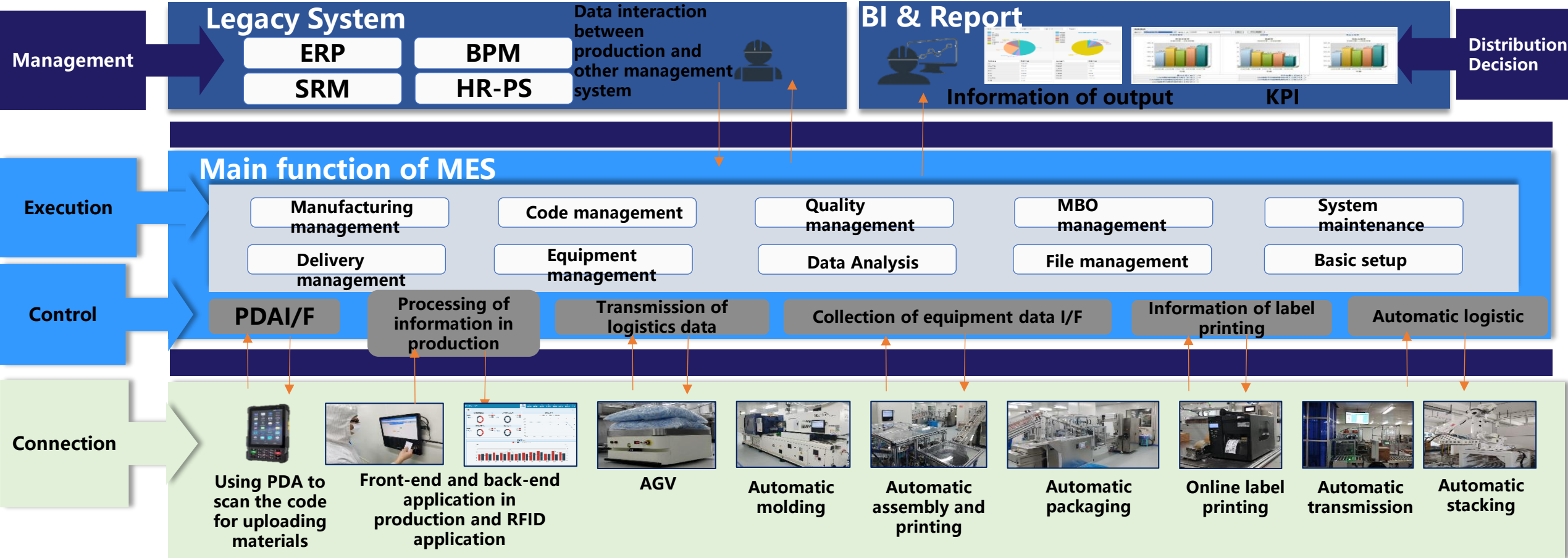
UDI database



UDI coding system



UDI traceability system





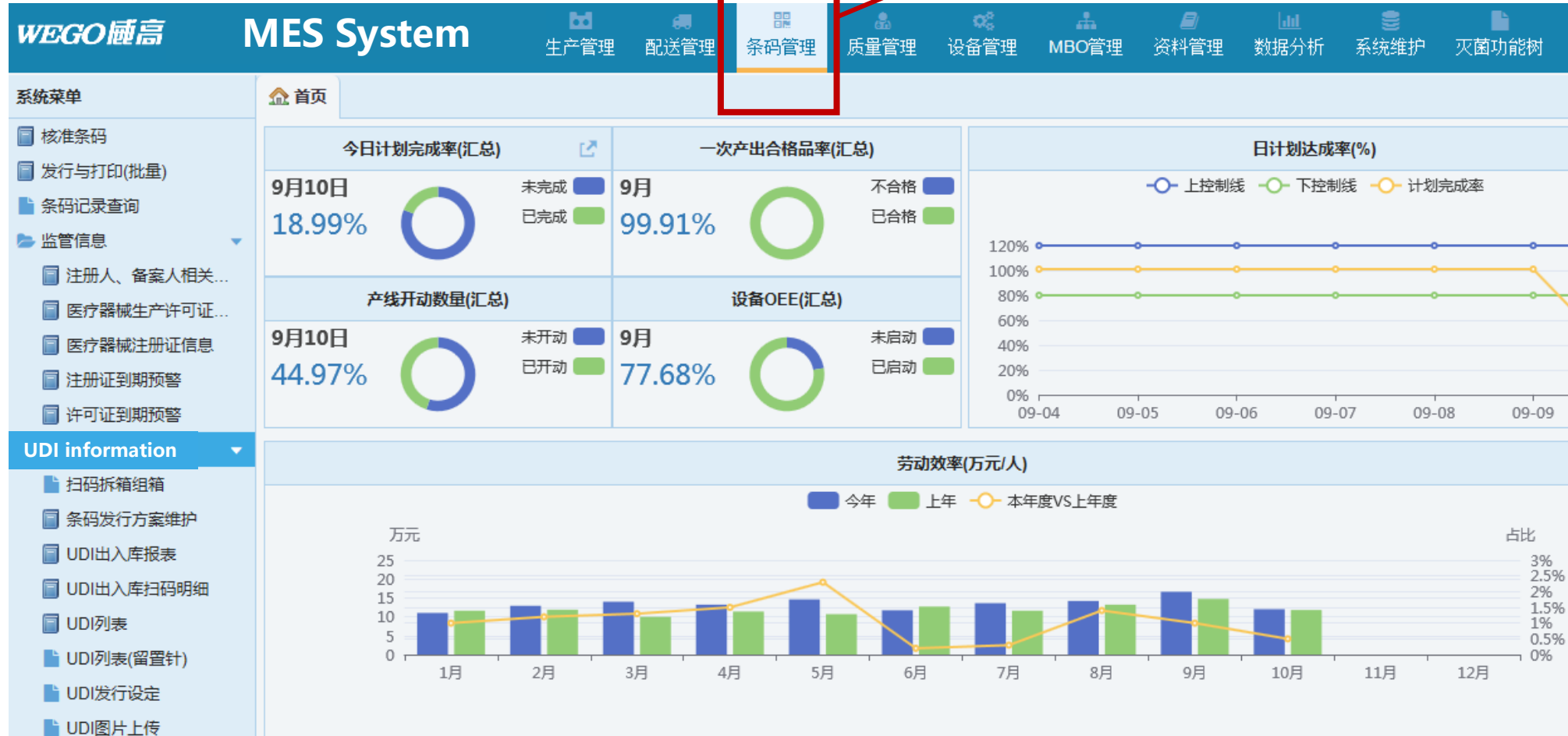
UDI Database



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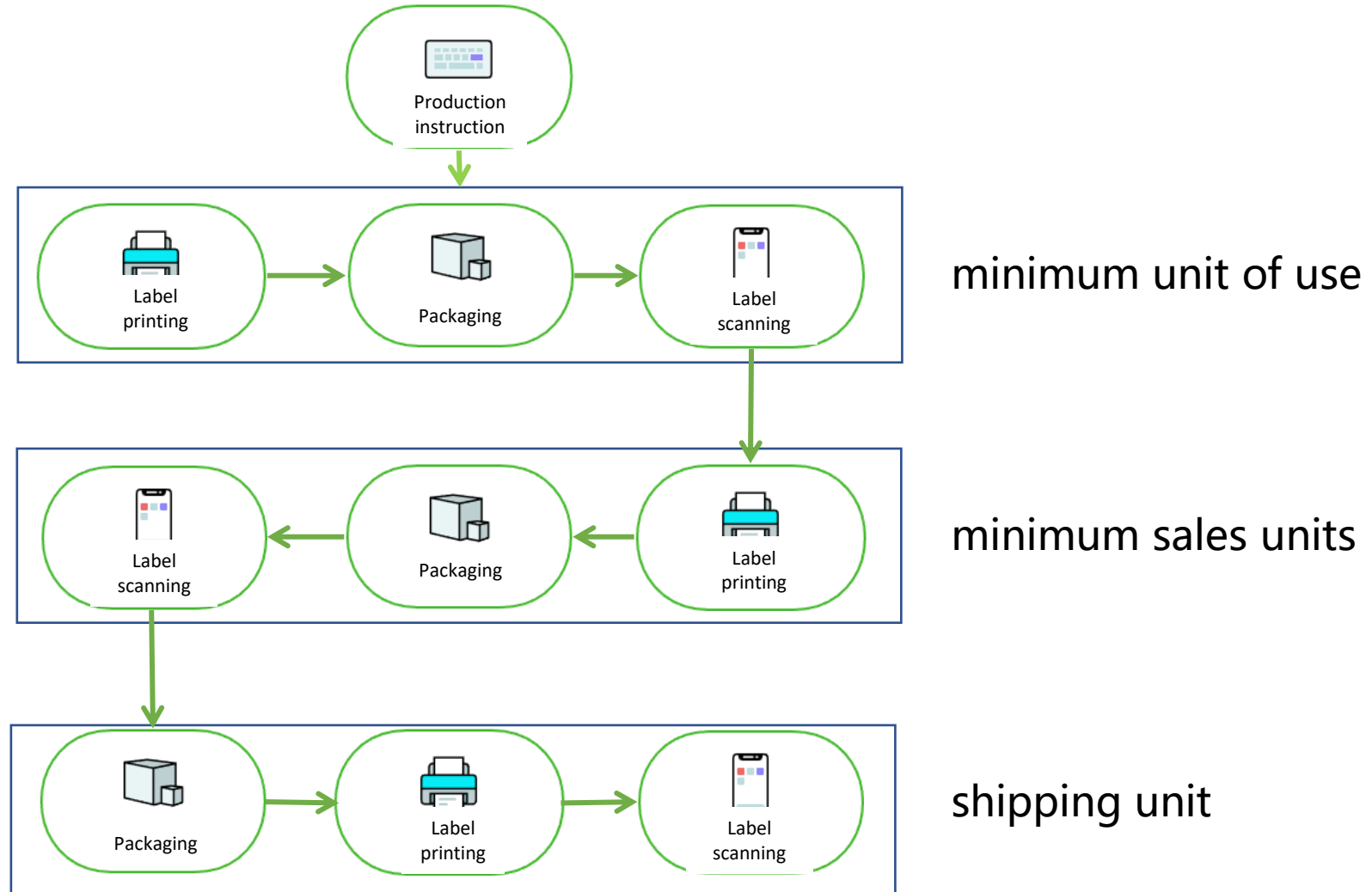
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Code management





UDI Coding System





UDI Coding System



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WEGO 威高 MES System

生产管理 配送管理 **条码管理** 质量管理 设备管理 MBO管理 资料管理 数据分析 系统维护 灭菌功能树

系统菜单 首页 条码发行方案维护 x issuing and printing

核准... 发行... 条码... 监管... 注... 医... 医... 注... 许... UDI...

账簿信息*: 医用制品集团, 专用输液器分公司 生产日期*: 2021-09-10 至*: 2021-09-10

包装级别: 大包装 状态: --请选择-- 班次: 白班

| 序号 | 账簿 | 包装级别 | 生产指令号 | 发行状态 | 计划订单号 | 生产车间 | 产品编码 | 产品名称 | 产线 | 灭菌批号... | 检验员 | 灭菌... |
|----|----------|------|---------------------|------|-----------------|-------|---------------|------------|---------|---------|-----|-------|
| 1 | 专用输液器分公司 | 大包装 | PR2021082300479-001 | 已发行 | PR2021082300479 | U组装六班 | 01.01.36.1965 | ZPQ低密度... | 组六包装13线 | 无 | 无 | 无 |
| 2 | 专用输液器分公司 | 大包装 | PR2021090100377-001 | 已发行 | PR2021090100377 | U组装六班 | 01.01.48.1573 | TPE微调(A... | 组六包装13线 | 无 | 无 | 无 |
| 3 | 专用输液器分公司 | 大包装 | PR2021090900037-001 | 已发行 | PR2021090900037 | U组装六班 | 01.01.41.1775 | ZPQTPE避... | 组六包装14线 | 无 | 无 | 无 |
| 4 | 专用输液器分公司 | 大包装 | PR2021090100409-003 | 已发行 | PR2021090100409 | U组装六班 | 01.01.36.1984 | 低密度(A2... | 组六包装14线 | 无 | 无 | 无 |
| 5 | 专用输液器分公司 | 大包装 | PR2021090100470-001 | 已发行 | PR2021090100470 | U组装六班 | 01.01.36.1973 | ZPQ低密度... | 组六包装14线 | 无 | 无 | 无 |
| 6 | 专用输液器分公司 | 大包装 | PR2021090100459-001 | 已发行 | PR2021090100459 | U组装二班 | 01.01.38.1628 | 避光(A25-... | 组二包装15线 | 无 | 无 | 无 |
| 7 | 专用输液器分公司 | 大包装 | PR2021090100414-001 | 已发行 | PR2021090100414 | U组装二班 | 01.01.38.1628 | 避光(A25-... | 组二包装15线 | 无 | 无 | 无 |
| 8 | 专用输液器分公司 | 大包装 | PR2021090100413-002 | 已发行 | PR2021090100413 | U组装五班 | 01.01.36.2004 | 低密度(A2... | 组五包装11线 | 无 | 无 | 无 |
| 9 | 专用输液器分公司 | 大包装 | PR2021090100413-001 | 已发行 | PR2021090100413 | U组装五班 | 01.01.36.2004 | 低密度(A2... | 组五包装11线 | 无 | 无 | 无 |
| 10 | 专用输液器分公司 | 大包装 | PR2021090100361-001 | 已发行 | PR2021090100361 | U组装五班 | 01.01.36.2005 | 低密度(A2... | 组五包装11线 | 无 | 无 | 无 |
| 11 | 专用输液器分公司 | 大包装 | PR2021090100322-001 | 已发行 | PR2021090100322 | U组装五班 | 01.01.36.1988 | 低密度(A2... | 组五包装11线 | 无 | 无 | 无 |
| 12 | 专用输液器分公司 | 大包装 | PR2021090100282-001 | 已发行 | PR2021090100282 | U组装五班 | 01.01.36.1937 | 低密度(A1... | 组五包装11线 | 无 | 无 | 无 |

扩展功能 批量发行条码 批量删除条码

Code management



UDI traceability system



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WEGO 威高 Weigao supply chain traceability system

系统维护

资料管理

供应链追溯

统计报表

超级管理员

系统菜单

首页

系统配置

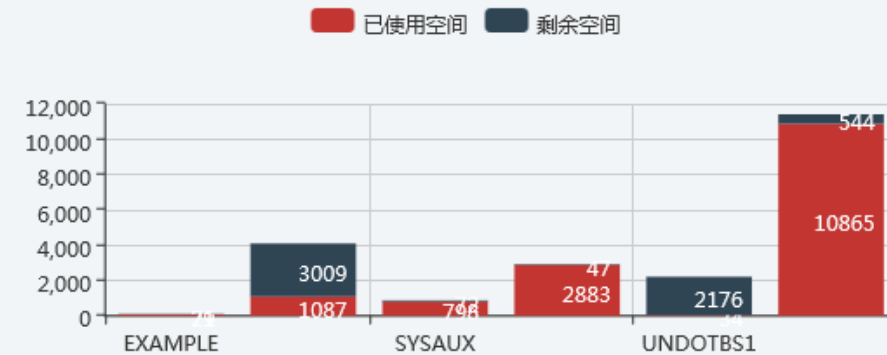
- 用户参数设置
- 系统参数设置
- 编码规则查询
- 成本中心管理
- 系统菜单管理
- 版本更新日志
- 用户报表管理

权限管理

日常维护

待办事宜

数据空间使用情况



接口运行情况

| 执行时间 | 数据/条 | 用时/秒 | 备注 | 参数时间 |
|------|------|------|----|------|
|------|------|------|----|------|

系统操作日志

| 操作时间 | 登录账号 | 功能 | 信息描述 |
|----------------------|-------|--------|-----------------|
| *2020-11-25 16:13:47 | 超级管理员 | 管理架... | 修改菜单【285】 |
| *2020-06-17 16:06:40 | 超级管理员 | 管理架... | 修改菜单【284】 |
| *2020-06-17 16:06:26 | 超级管理员 | 管理架... | 修改菜单【283】 |
| *2020-06-17 16:06:03 | 超级管理员 | 管理架... | 修改菜单【282】 |
| *2020-06-17 16:02:46 | 超级管理员 | 管理架... | 修改菜单【28】 |
| *2020-06-10 16:48:22 | 超级管理员 | 用户角色 | 修改角色【UDI追溯】的功能！ |

系统更新日志

System maintenance



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Opportunities for distributors

PART . 0 2

Significance of applying UDI for distributors

01

Management refinement

Distributors play a critical role in information circulation and product circulation in the medical device supply chain. UDI enables distributors to realize fine management of the whole process throughout the first operation of the product, procurement, acceptance into the warehouse, warehousing, sales to after-sales, and provides basic information guarantee for distributors.

02

Improvement of the efficiency of information capture

After the application of UDI, distributors can quickly identify the static and dynamic information in the UDI by means of code scanner gun, portable PDA and other equipment, and achieve intelligent access to storage, warehousing and other aspects of the process. This greatly enhances the efficiency of capturing product information, and enables a visual, intelligent, and transparent supply chain, finally facilitates an efficient operating system of supply chain.



Weigao traceability platform for supply chain



Scan UDI



Transmit into the aeration area



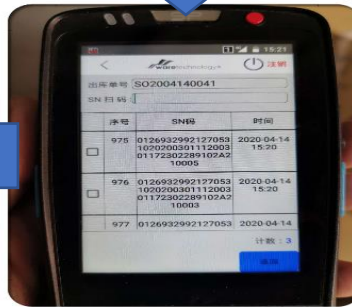
Scan allocation sheet



Scan UDI to put into product warehouse



Scan allocation sheet



Scan UDI to transmit out of the aeration area

The traceability platform for supply chain created by Weigao Group is connected with the MES system of the manufacturing management operation platform and the enterprise management system, which realizes the comprehensive management of medical device data in warehousing management and logistics. The warehousing management system of distribution has been correlated with the medical supplies management system of medical institutions through the data transmission protocol to achieve data sharing, which facilitates the establishment of a modernized logistics system for distributors.



Weigao traceability platform for supply chain



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WEGO 威高 Weigao supply chain traceability system

系统菜单 | 首页 | Traceability information | 供应链追溯 | 统计报表 | 威高

追溯信息 | 包装信息 | 产品信息

UDI条码: (01)26932992101459(10)20191211(11)191216(17)221210(91)12A(21)0041

| | | | | | |
|--------|---------------------|-------|----------|--------|------------------------|
| 产品名称* | 一次性使用无菌耐辐照溶药用注射器 带针 | 产品规格* | 50ml | 注册证编码* | 鲁械注准 20152140133 |
| 产品批号* | 20191211 | 生产日期* | 191216 | 失效日期* | 221210 |
| 注册证失效* | 2024/7/30 0:00:00 | 分类编码* | 14-01-02 | 分类名称* | 血管内输液器械 |
| 装量* | 200 | 灭菌方式* | 辐照灭菌 | 企业地址* | 山东省威海市火炬高技术产业开发区兴山路18号 |
| 存储条件* | | | | | |

UDI traceability record

- 2019/12/16 0:00:00 出厂时间: 山东威高集团医用高分子制品股份有限公司
- 2020/1/1 9:40:00 入库: 山东威高北京库房入北京库房
- 2020/1/8 12:00:00 出库: 山东威高北京库房出北京库房
- 2020/1/9 11:20:00 入库: 国药华润北京库房入华润库房
- 2020/1/10 15:00:00 出库: 国药华润北京库房出华润库房
- 2020/1/10 15:01:00 入库: 国药华润北京库房入急诊科门诊, 入肺移植科病区, 入心脏内科CCU, 入中医消化科病区, 入消化内科病区, 入骨科二部(脊柱外科病区)



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Opportunities for medical institutions

PART . 03



Significance of applying UDI for medical institutions



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Supply data specification

UDI enables medical institutions to establish a data dictionary for supplies, integrate coding standard, enhance information connection and traceability, facilitate the cost control and risk prevention.

Supply management improvement

UDI helps medical institutions to realize life-cycle traceability of products, so as to enhance medical quality assurance and prevent non-compliant use.

Information sharing

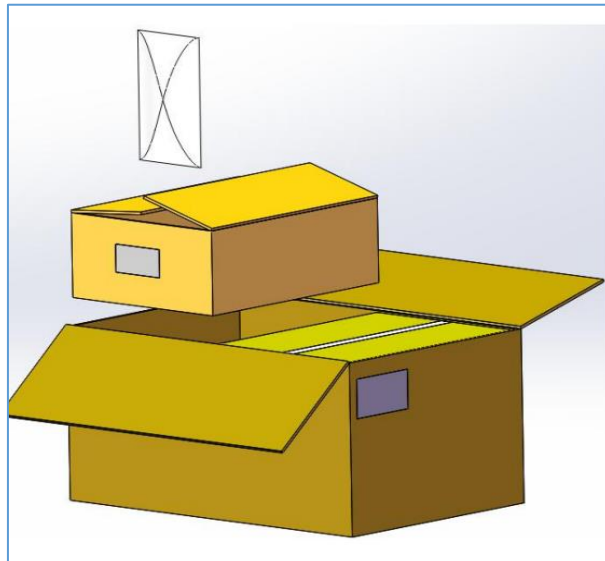
UDI empowers medical institutions to cope with the issue of information silos, bring about data interaction across departments, improve inventory and expense management efficiency, and reduce healthcare risk.





Application of Weigao UDI in medical institutions

UDI has been assigned and linked to all levels of packaging of Weigao' s medical products. The information on all levels of packaging can be displayed when medical staff scan the UDI on one single package, which enhances the fine management of medical institutions. The requirement of "One device marked by one UDI" allows medical institutions to charge by one item, which ensures the traceability of storage, patient use and billing consumption of consumables in hospitals and effectively reduces the risk of the quality and clinical use of medical devices.



Connection between levels of packaging

最小使用单元

(01) 0 6932992 12705 9 (10) 20200301 (11) 200301 (17) 230228 (91) 02A (21) 0001
 型号规格: 进气式(精密)5µm
 配置: 6EJM-KL-Q ZPQZY HJM
 数量: 1支 生产日期: 2020-03-01
 生产批号: 批20200301 失效日期: 2023-02-28

最小销售单元

(01) 1 6932992 12705 6 (10) 20200301 (11) 200301 (17) 230228 (91) 02A (21) 0001
 型号规格: 进气式(精密)5µm
 配置: 6EJM-KL-Q ZPQZY HJM
 数量: 50支 生产日期: 2020-03-01
 生产批号: 批20200301 失效日期: 2023-02-28

运输单元

一次性使用输液器
 (01)26932992127053(10)20200301(11)200301(17)230228(91)02A(21)0001
 数量: 200支 毛重: 7.5Kg 体积: 670X450X330 (mm³)
 型号规格: 进气式(精密)5µm
 配置: 6EJM-KL-Q ZPQZY HJM
 生产批号: 批20200301 失效日期: 2023-02-28
 生产日期: 2020-03-01 **REF** 01.01.09.6041

One device marked by one UDI

扫码结果
 码制: GS1 DataMatrix
 UDI: (01)26932992155674(10)20240721(11)240721(17)260720(91)08A(21)0001
 编码体系: GS1
UDI解析数据
 产品标识(01): 26932992155674
 生产批号(10): 20240721
 生产日期(11): 240721
 失效日期(17): 260720
 公司内部信息(91): 08A
 序列号(21): 0001

产品信息
 产品名称: 一次性使用袋式输液器
 规格型号: 250mL 0.7x22.5 TWLB
 产品包装级别: 大包装
 包装内含小一级产品详情: 20 [包装内详情>](#)
 生产批号: 20240721
 生产日期: 2024年07月21日
 失效日期: 2026年07月20日
 产品类别: 耗材
 器械类别: 器械
 分类编码: 14-02-05
 产品货号或编号: 01.01.02.2501
 产品描述: 2D-0.7

 [关于](#)

Information accessible



Challenges confronted by all the parties

PART . 04



Challenges confronted by all the parties

01

Challenges faced by manufactures

Differences in manufacturers' understanding of UDI lead to poor design and various data quality standards, so that manufacturers shall enhance their understanding of regulations and specifications.

02

Lack of momentum for distributors to apply UDI

It' s necessary for distributors to input resources and strengthen capacity building, so as to bring about UDI system improvement and awareness of UDI.

03

Difficulties in the application of UDI in medical institutions

The complex UDI system reorganization requires coordinated efforts made by various departments under appropriate conditions.



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Thank you