

TQS

Traceable Quality System

**In pursuit of the new EU regulations -
TQS: the modern way of serialization.**

Competence in dynamic weighing.





About one in two medicines are counterfeited



DIE WELT

Jedes zweite Medikament aus dem Netz ist gefälscht

Jedes zweite im Internet verkaufte Medikament ist gefälscht. Das schätzt ein Internisten-Verband. Der illegale Handel ist lukrativ. Die Gewinnspanne bei illegalem Viagra liegt bei 47.000 Prozent.



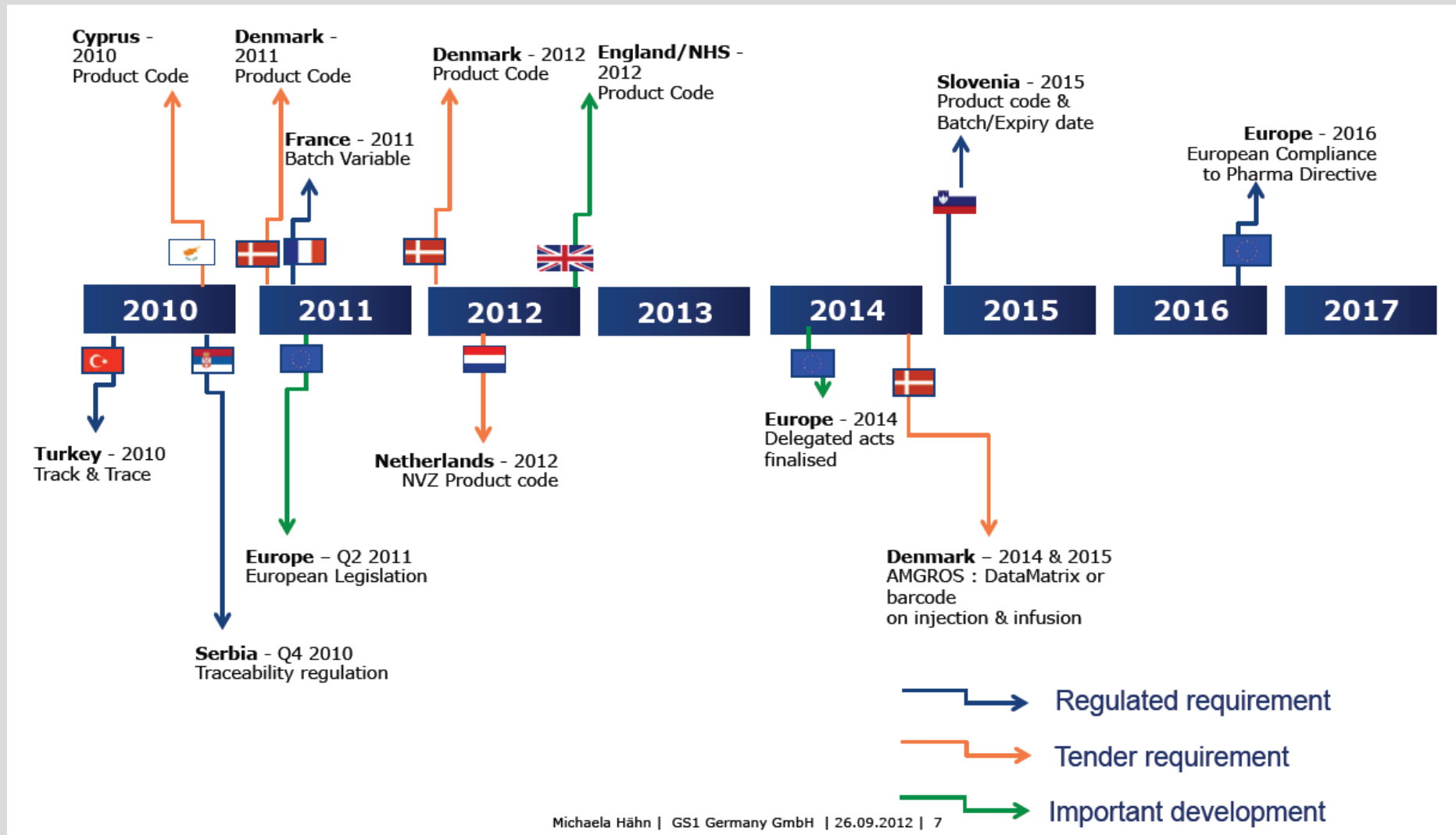
Foto: picture-alliance/ dpa Gefälschte Viagra-Tabletten haben eine hohe Gewinnspanne



Compliance Requirements EU



Traceable Quality System [TQS]



Source: GS1 Healthcare 2011

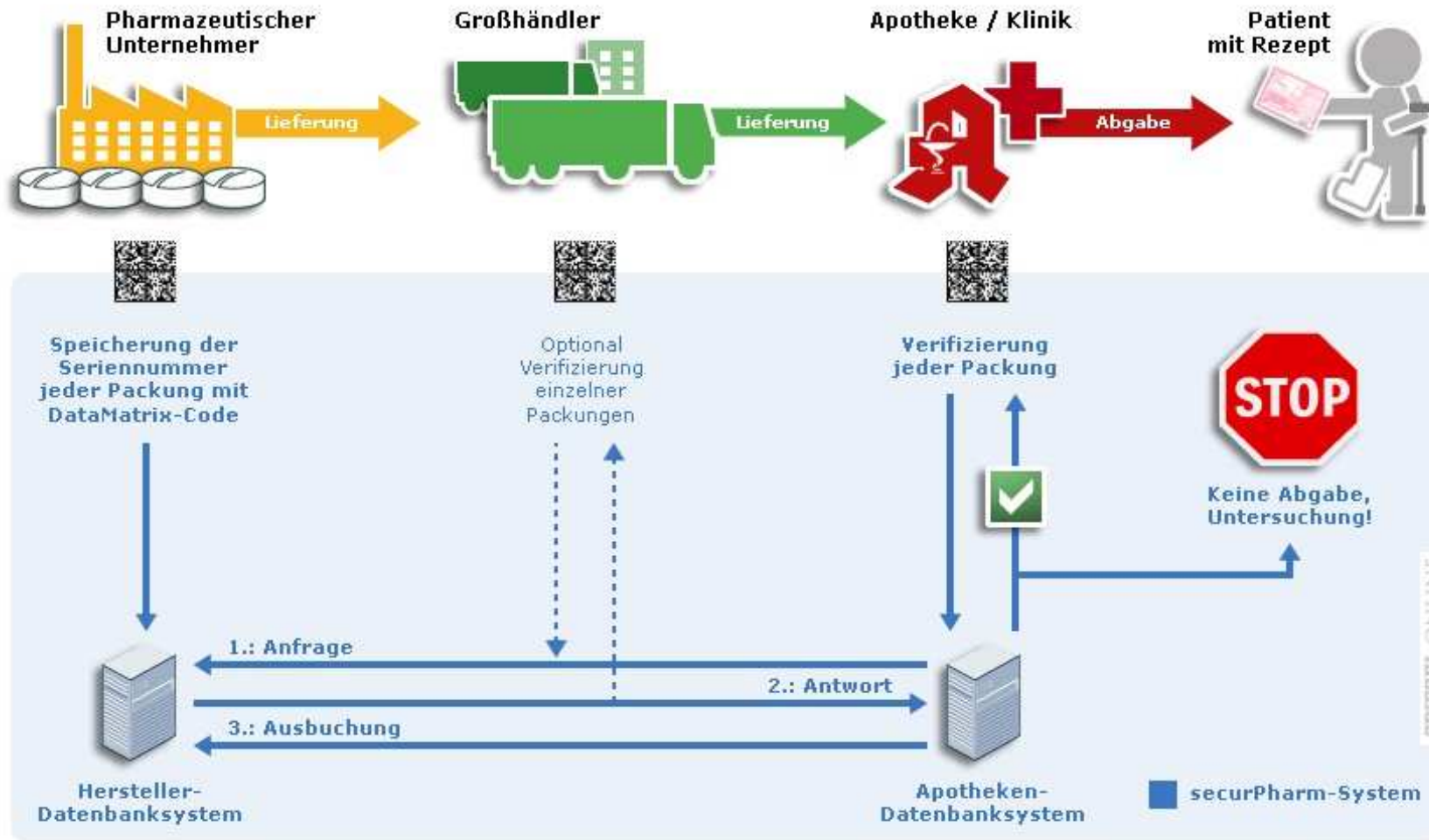


Germany - securPharm



Neues Sicherheitssystem

Die Echtheit von Arzneimitteln in der Apotheke soll überprüfbar werden



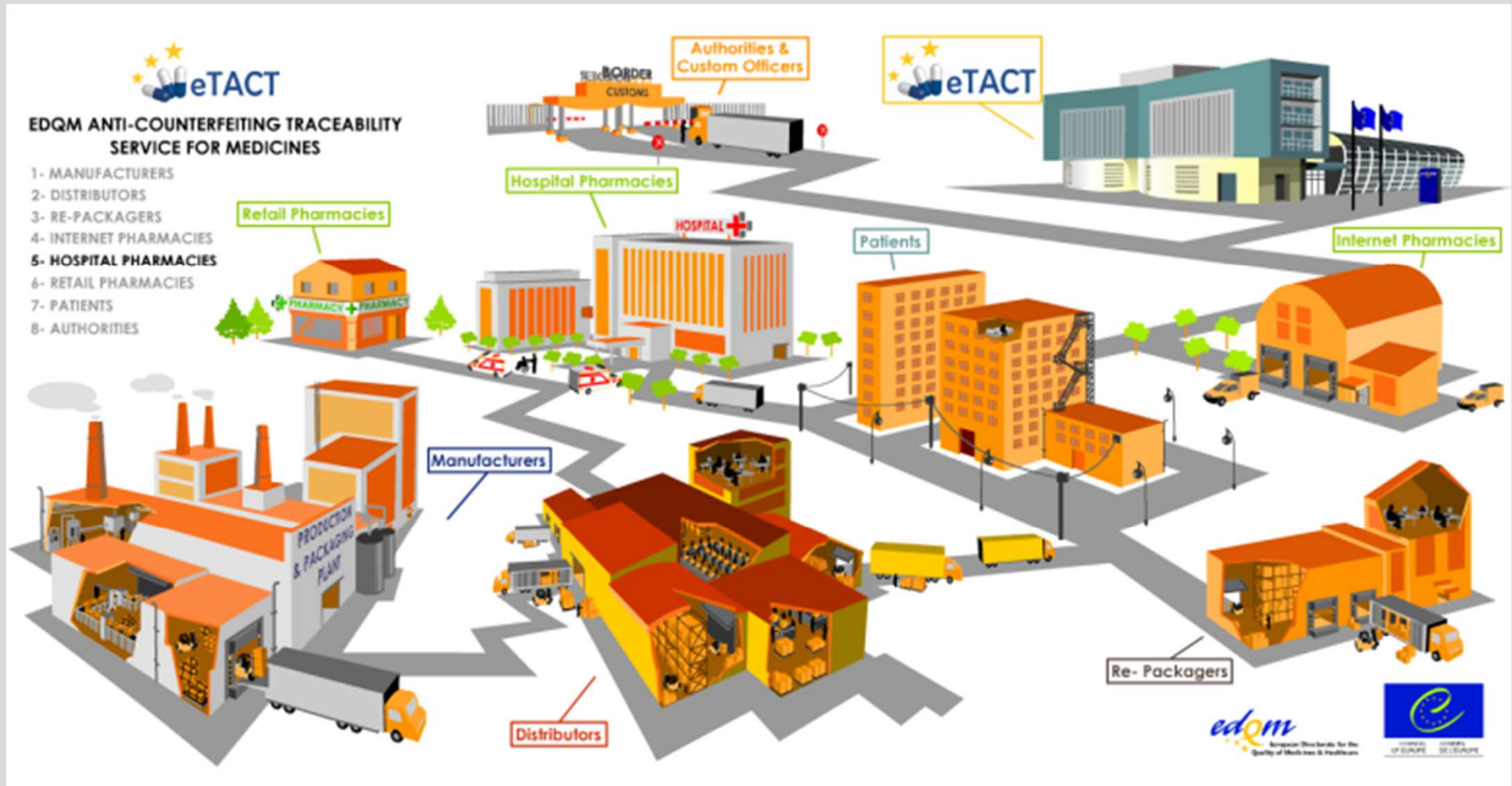
Quelle: Securpharm, Das End-to-End-Kontrollsystem zur Abwehr gefälschter Arzneimittel, 10/2011



Europe – eTACT (EDQM)



Traceable Quality System [TQS]

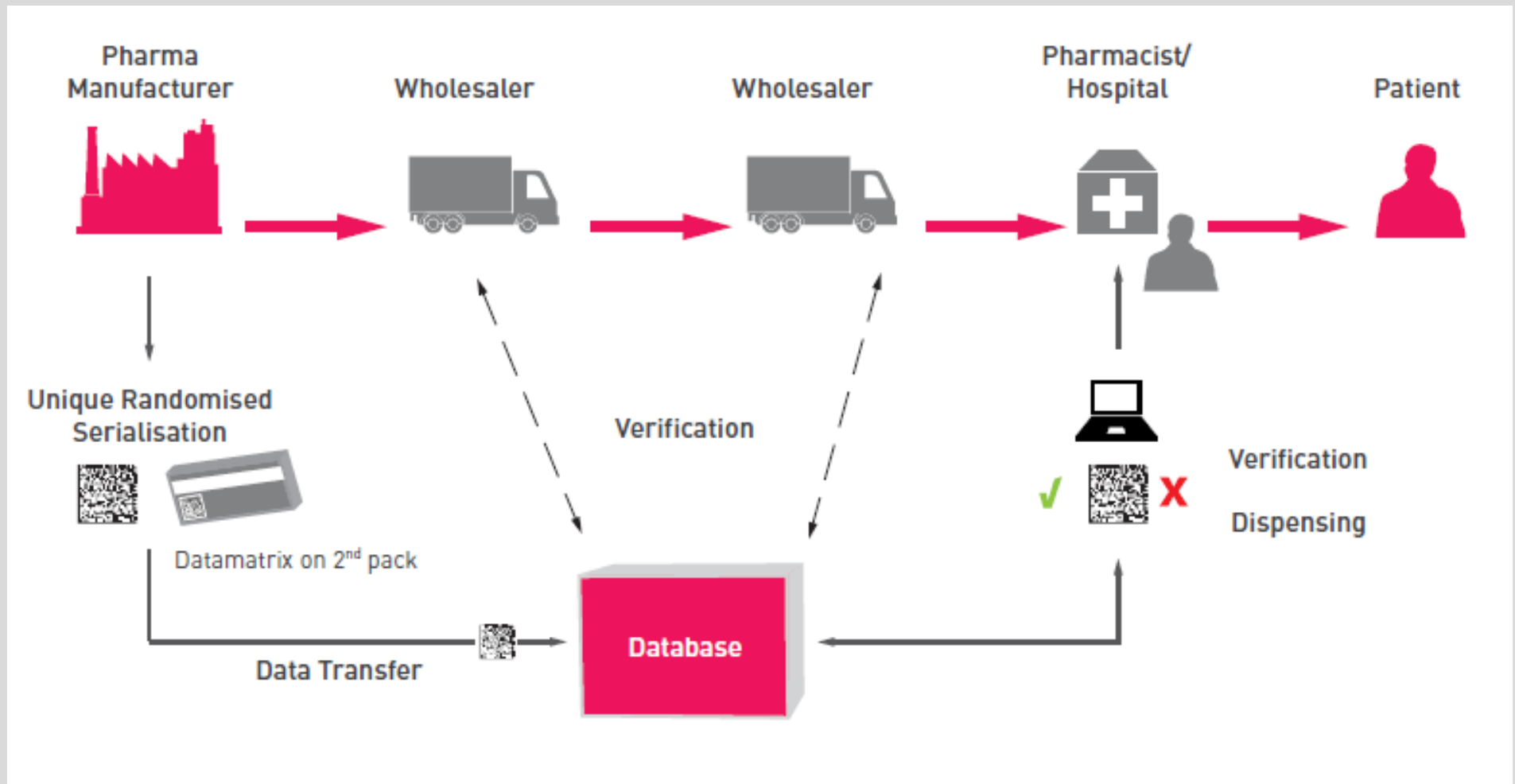


Source: EDQM



Europe - ESM (efpia)

Traceable Quality System [TQS]



Source: efpia



Different Countries → Different Codes



CIP 3400930000120
EXP 12/2013
LOT A12345

France: CIP 13 Code without s/n number



(01) 08691234567890
(21) 111111111123
(17) 131231
(10) A12345

Turkey: GS1 Data Matrix Code
with s/n number



中国药品电子监管码
09612 01700 00010 00001
电话查询: 95001111
短信查询: 106695001111
网络查询: www.drugadmin.com

China: Code 128 C

Bundle Wipotecin 20mg

(01) 08691234567890 EXP: 131231
(21) 111111111123 LOT: A12345



(01)18691234567890(21)11111111225

Aggregation: GS1 128 Code



TQS-SP Serialization of Single Packs



Traceable Quality System [TQS]



User friendly
operator interface

15" TFT color
display to tilt

Stainless steel
cabinet covers
all components

Secure product
transport for high
grade coding &
inspection

Compact & space-
saving machine
design



TQS-HC-A

Serialization and Weighing



Traceable Quality System [TQS]

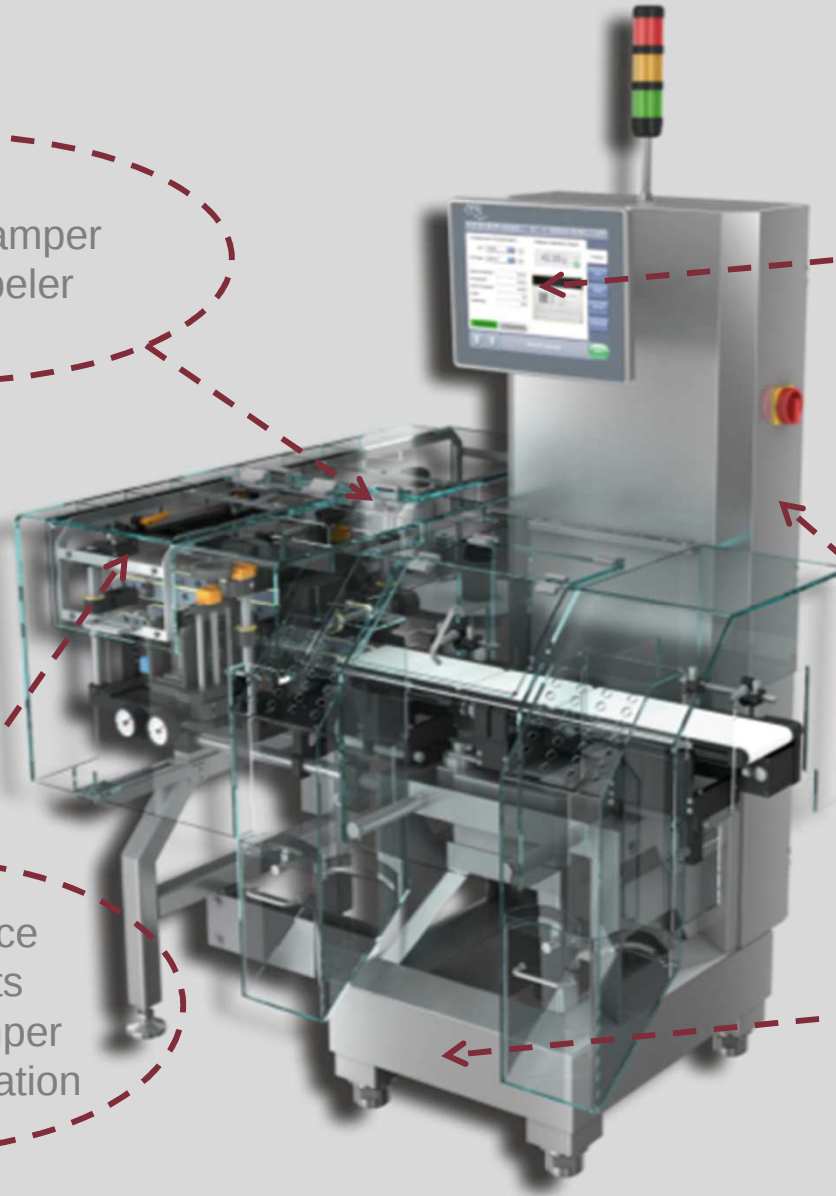
Integrated tamper
evident labeler

Single point of
operation for,
printer, camera,
checkweigher

Stainless steel
cabinet covers
all components

Track & Trace
components
including tamper
evident verification

Compact & space-
saving machine
design "2 in 1"

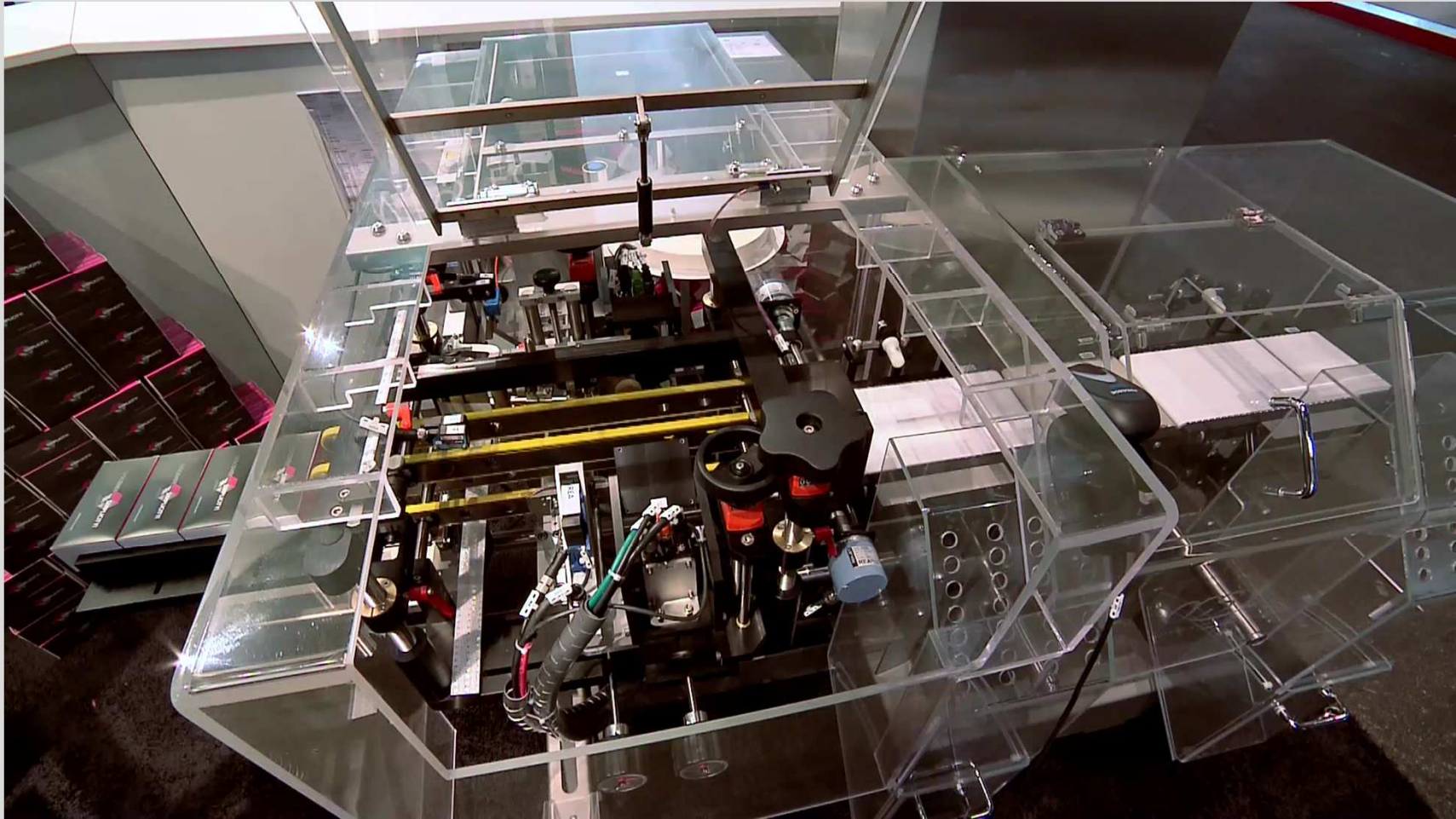




TQS-HC-A → LIVE



Traceable Quality System [TQS]

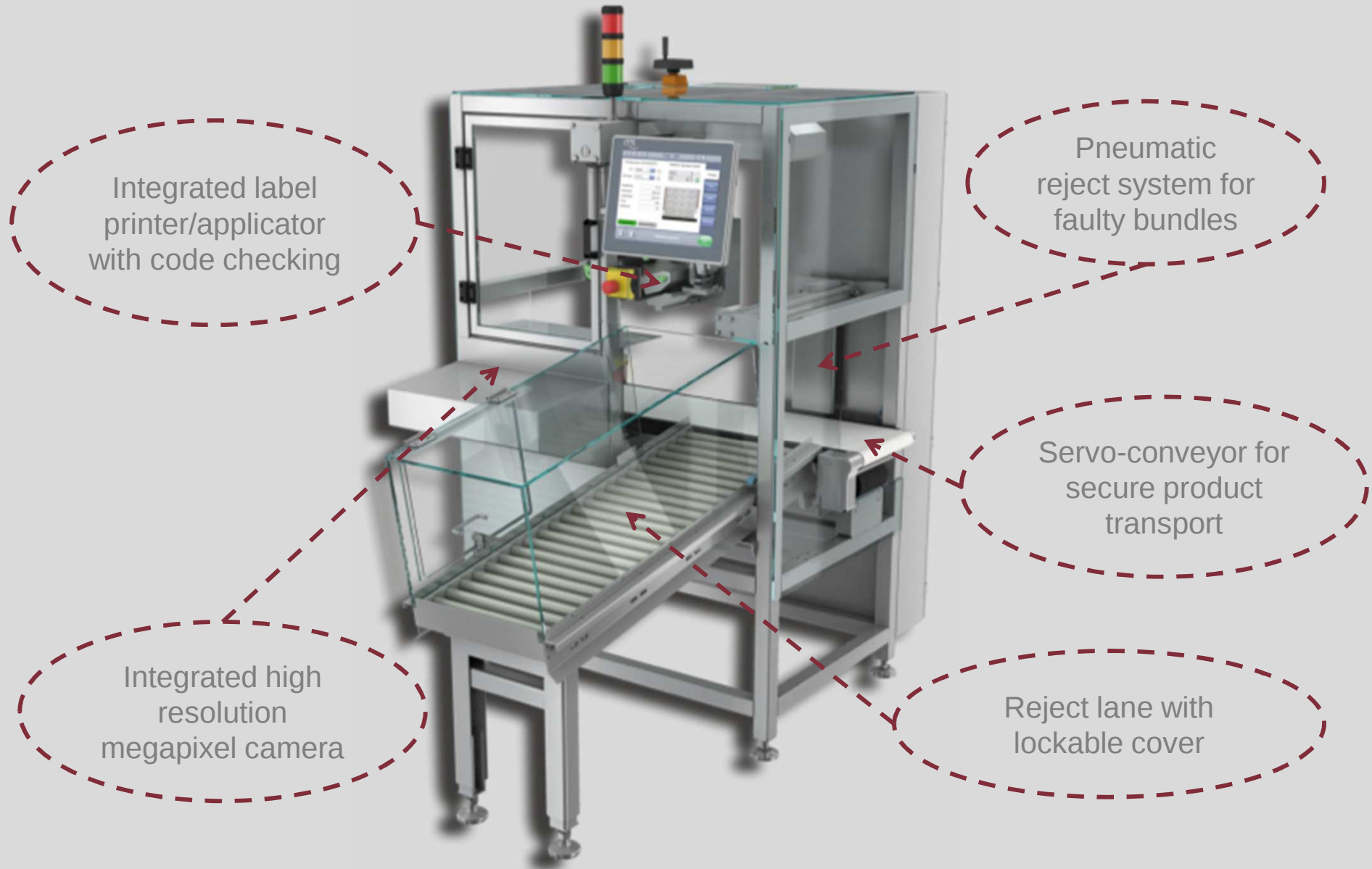




TQS-BP Aggregation for Bundle Packs



Traceable Quality System [TQS]



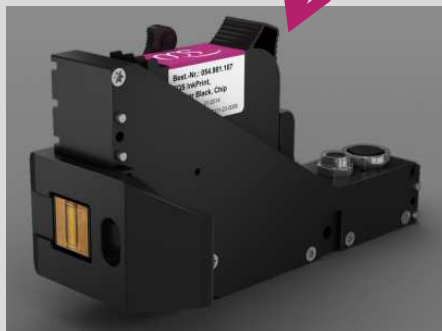


Fully integrated layouter



- Unique OCS user interface “WYSIWYG”
- Creating layout with automatic plausibility check
- No proprietary coding- and camera-software
- No additional HMI's or controllers to be operated

Traceable Quality System [TQS]

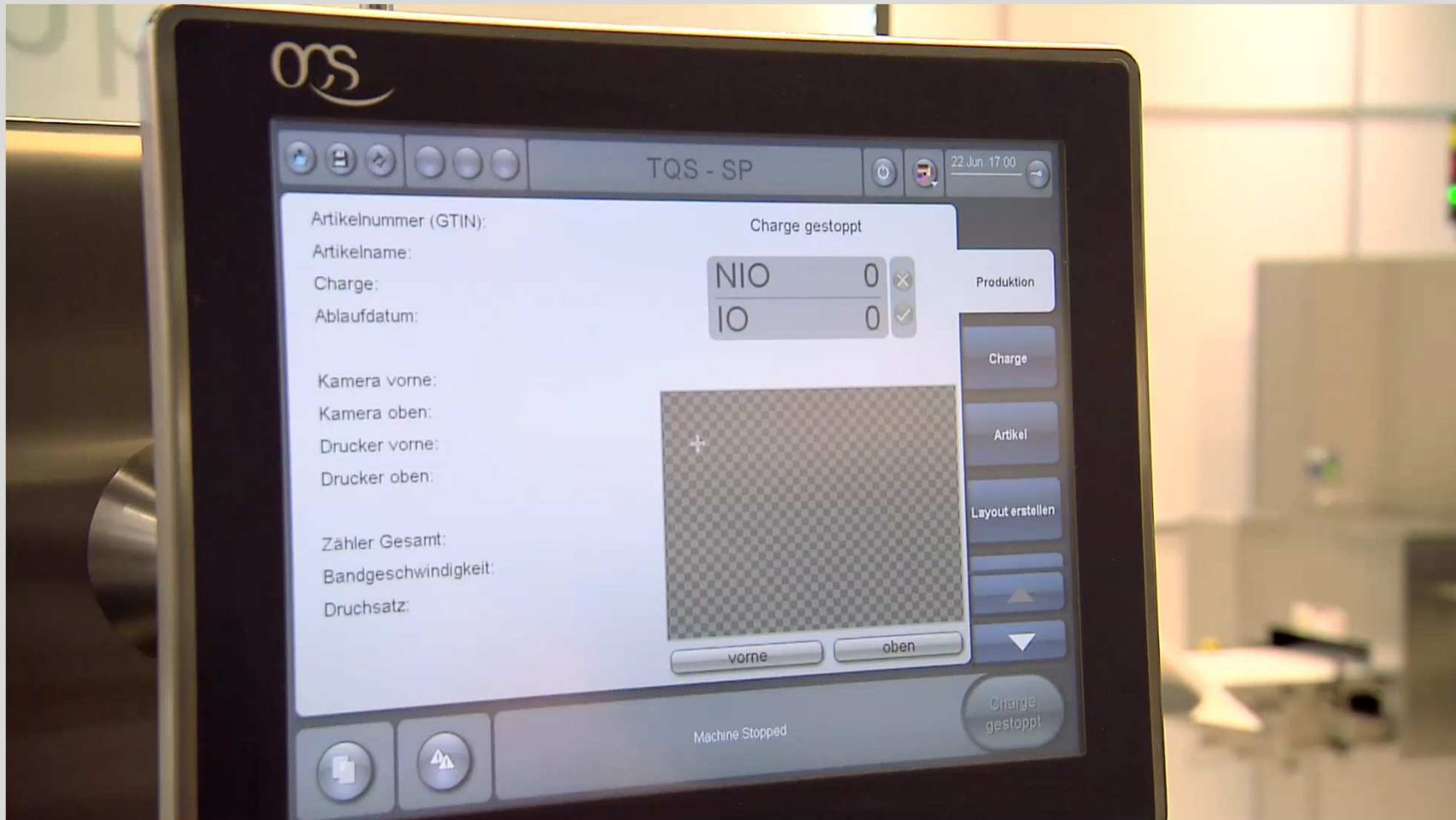




Fully Integrated Layouter → LIVE



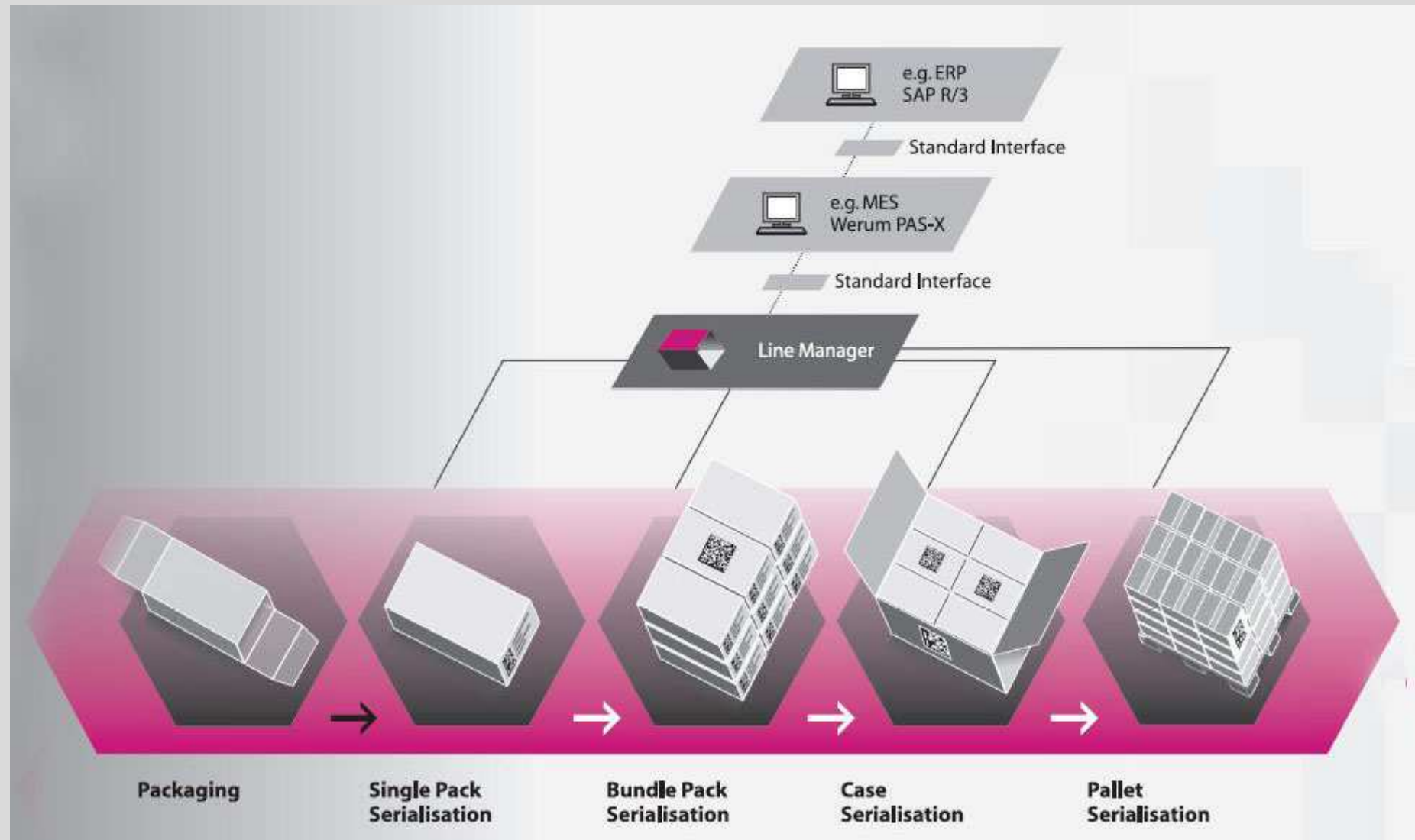
Traceable Quality System [TQS]





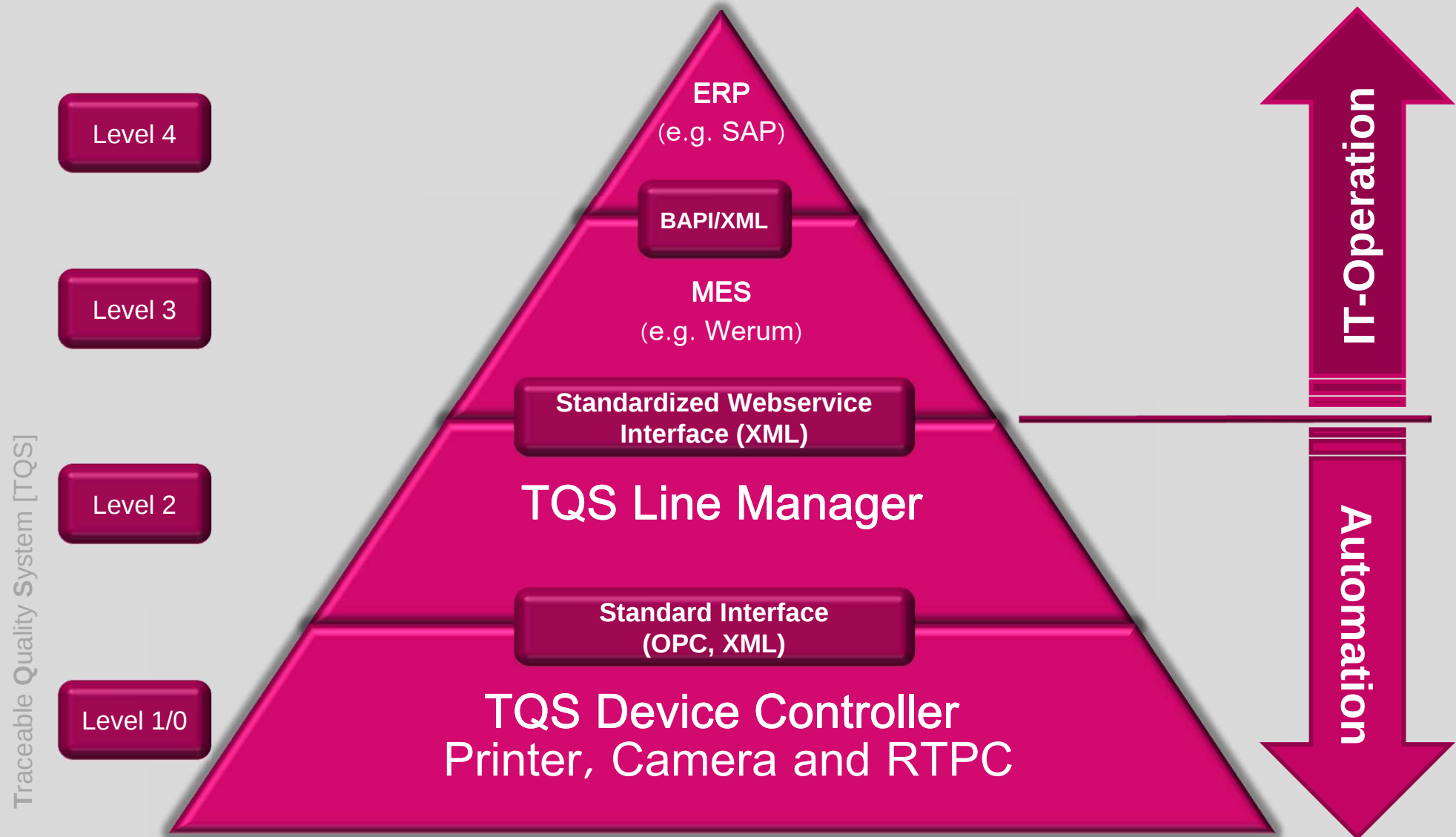
Track & Trace → TQS Principle

Traceable Quality System [TQS]





ISA-95 Architecture





Time-Saving and Cost-Reducing



- ✓ Cost-reducing first year → **EUR 420.000,00**
 - ✓ EUR 5.000,00 (Communication)
 - ✓ EUR 6.000,00 (IQ/OQ)
 - ✓ EUR 3.000,00 (Service)
 - ✓ EUR 2.000,00 (Training printer subsystem)
 - ✓ EUR 3.000,00 (Training camera subsystem)
 - ✓ EUR 1.000,00 (Subsystem troubleshooting)
 - ✓ EUR 400.000,00 (Layouter)
- ✓ Cost-reducing per every following year → **EUR 11.000,00**
 - ✓ EUR 5.000,00 (Communication)
 - ✓ EUR 2.000,00 (Training printer subsystem)
 - ✓ EUR 3.000,00 (Training camera subsystem)
 - ✓ EUR 1.000,00 (Subsystem troubleshooting)





OCS Checkweighers → LIVE



Traceable Quality System [TQS]





Thank you for your attention!

In case of any questions, please do not hesitate to get in contact with us:

Reto Gianotti

Business Manager Pharma

reto.gianotti@madosystemy.com

Włodzimierz Cieślar

Sales Manager

wlodzimierz@madosystemy.com