



Sebastian Mayer – *Product Manager Pharma & Healthcare*

HEUFT *spotter II* BFS – Blow-Fill-Seal ampoule inspection machine



GMP - Annex 1 Manufacture of Sterile Medicinal Products

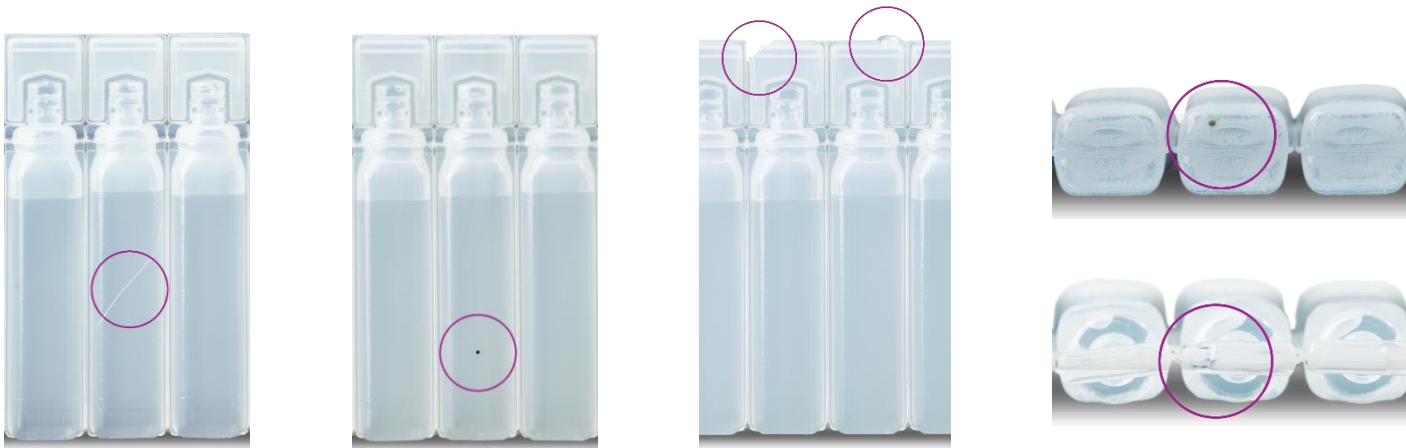
Finishing of sterile products

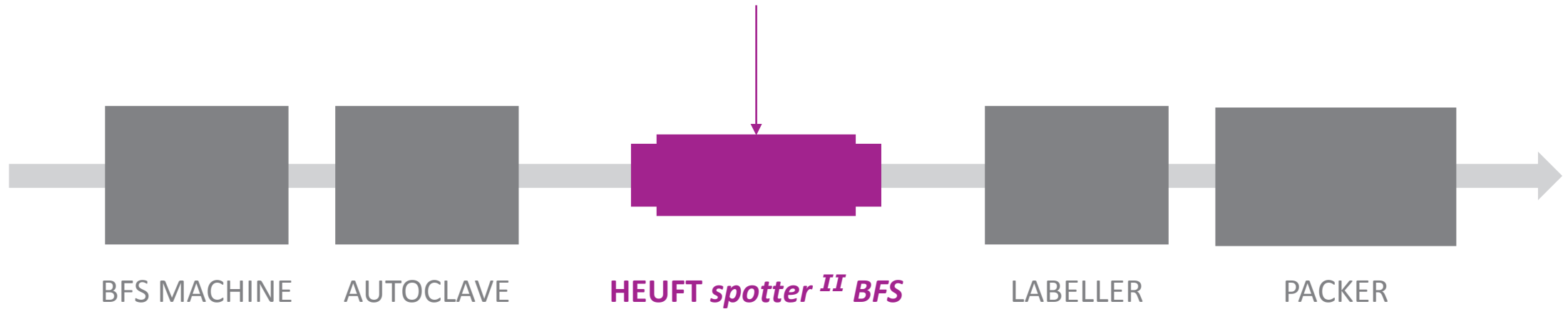
“(...) Containers closed by fusion, e.g. Form-Fill-Seal Small Volume Parenteral (SVP) & Large Volume Parenteral (LVP) bags, glass or plastic ampoules, should be subject to 100% integrity testing. (...)”



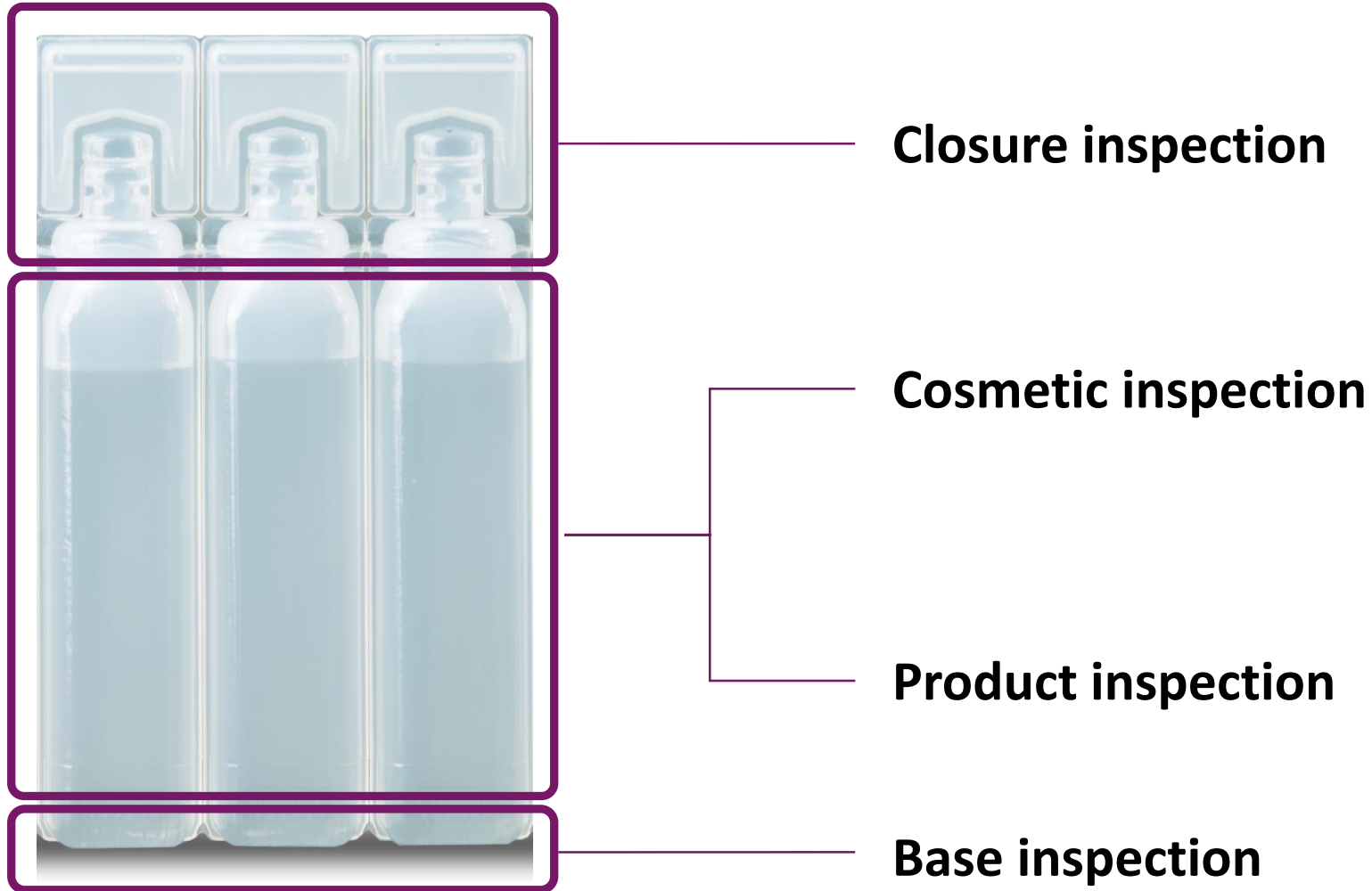
HEUFT *spotter II* BFS

All-around quality inspection of Blow-Fill-Seal ampoules based on the HEUFT *SPECTRUM II*.

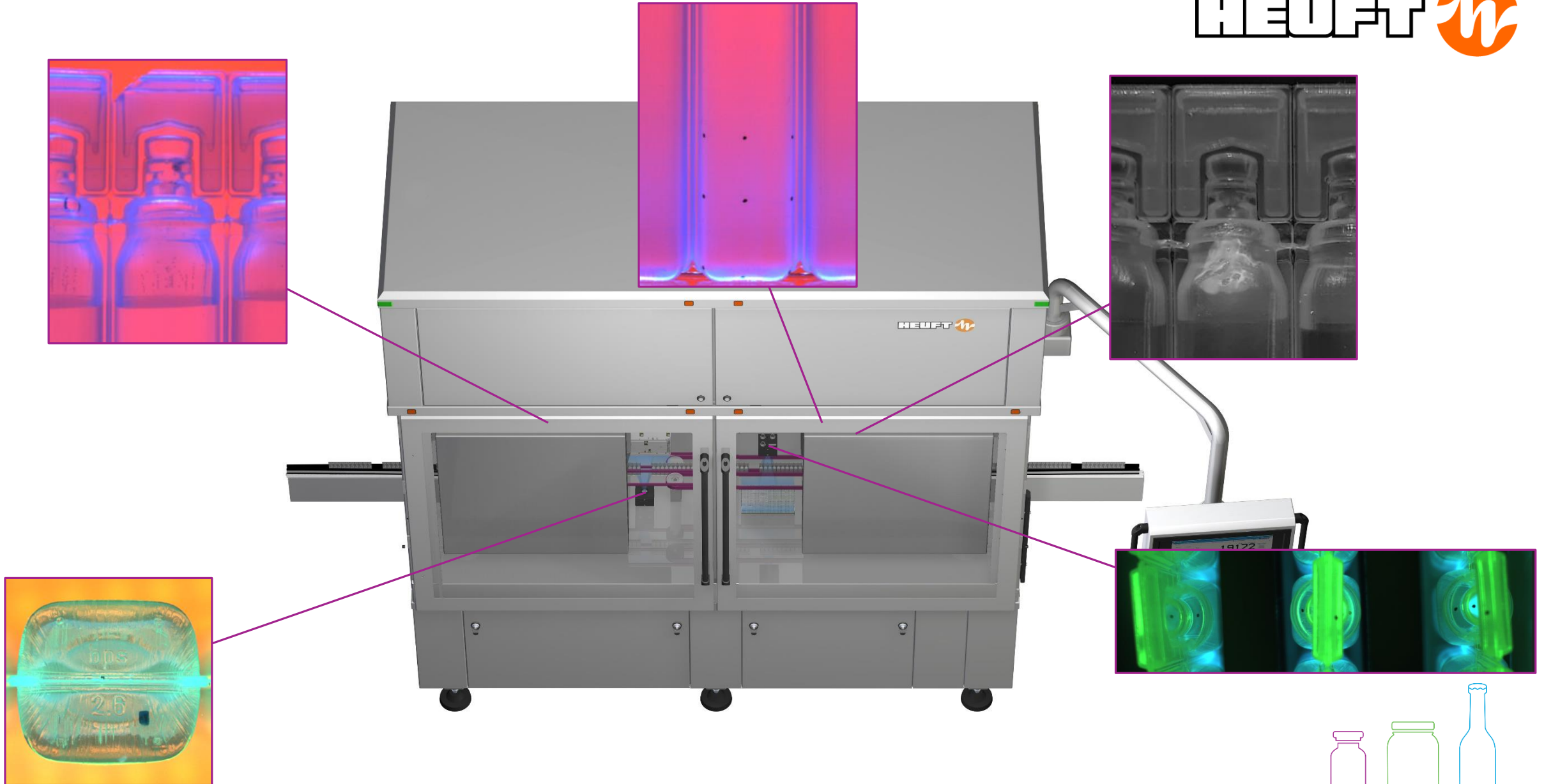


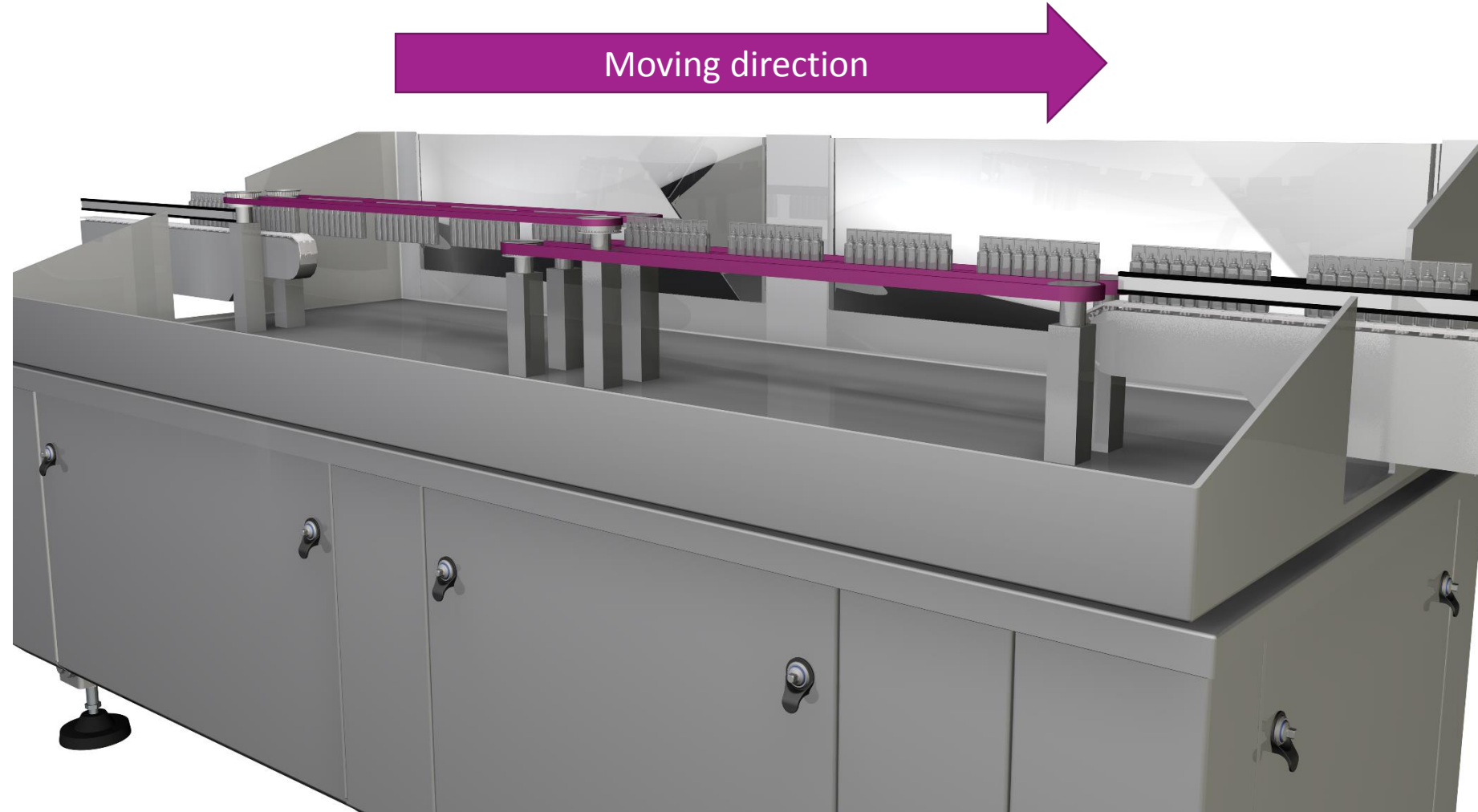


Line layout

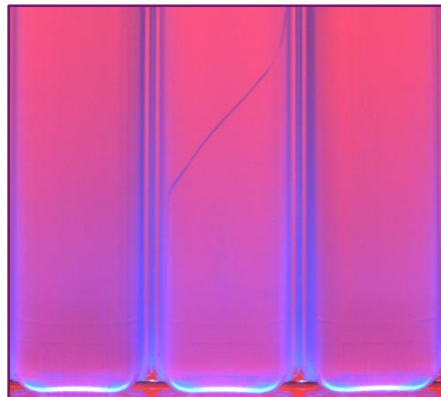


Inspection areas





Transportation method

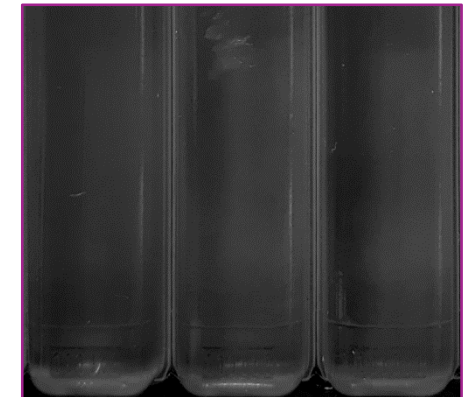
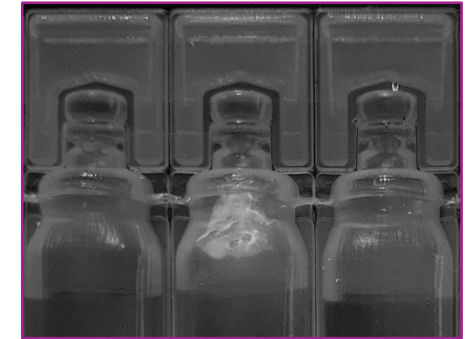


MCIP

(Multi Colour Image Processing)

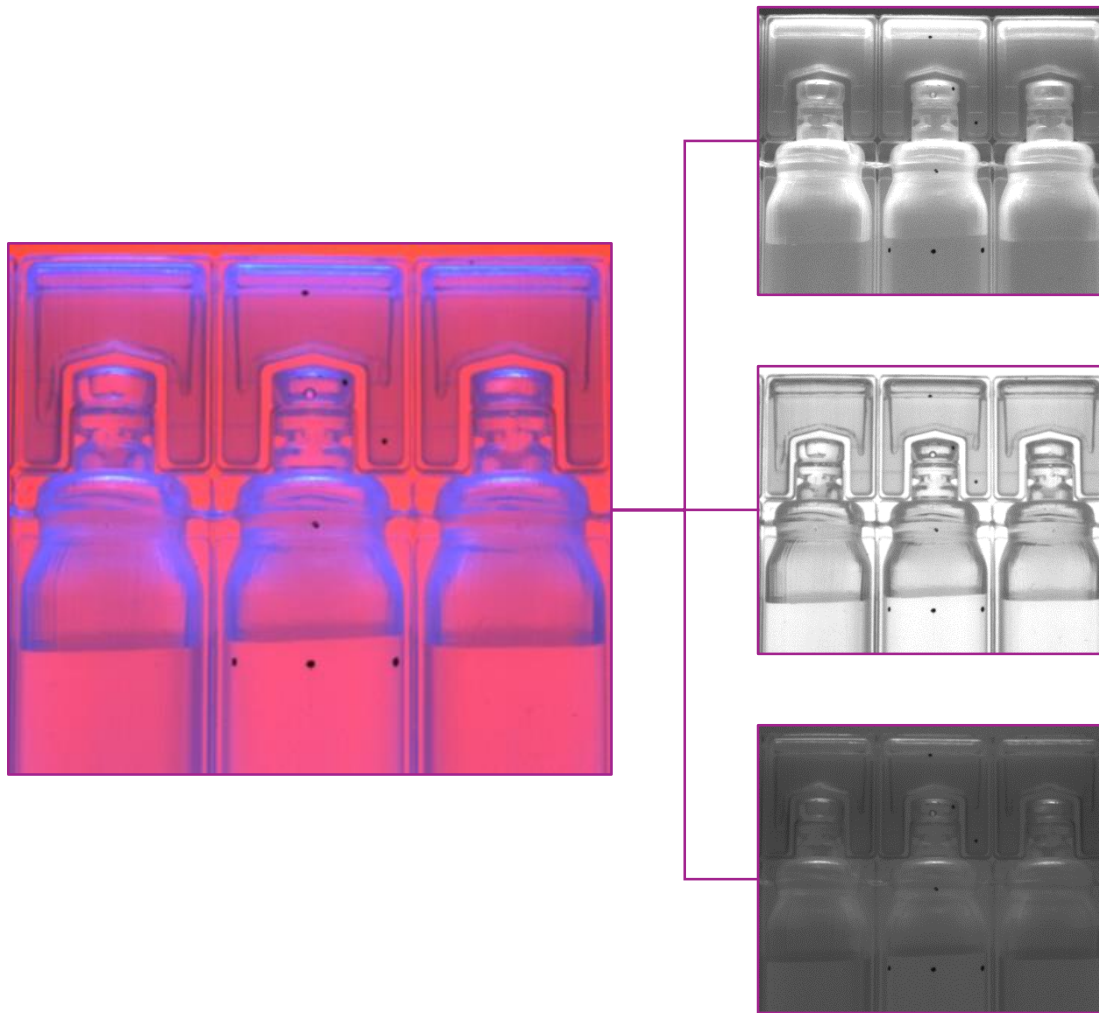
The sidewall inspection is divided into upper & lower sidewall inspection with multiple illumination principles

- Illumination principle for the detection of classical faults
- Special illumination principle for the detection of opaque greasy contamination



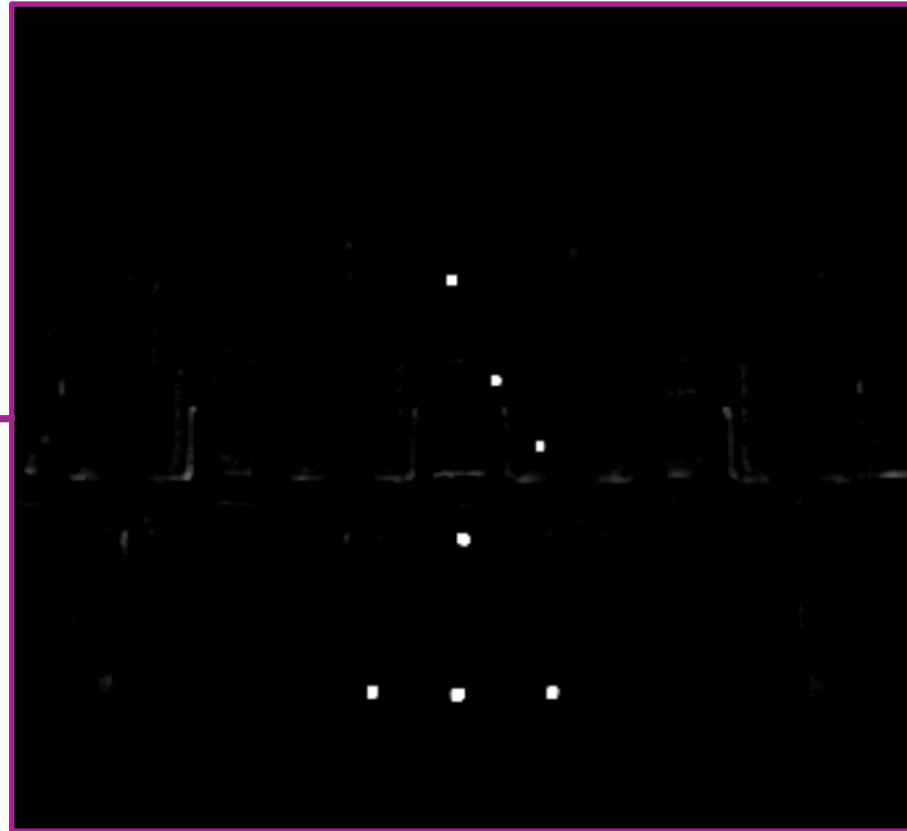
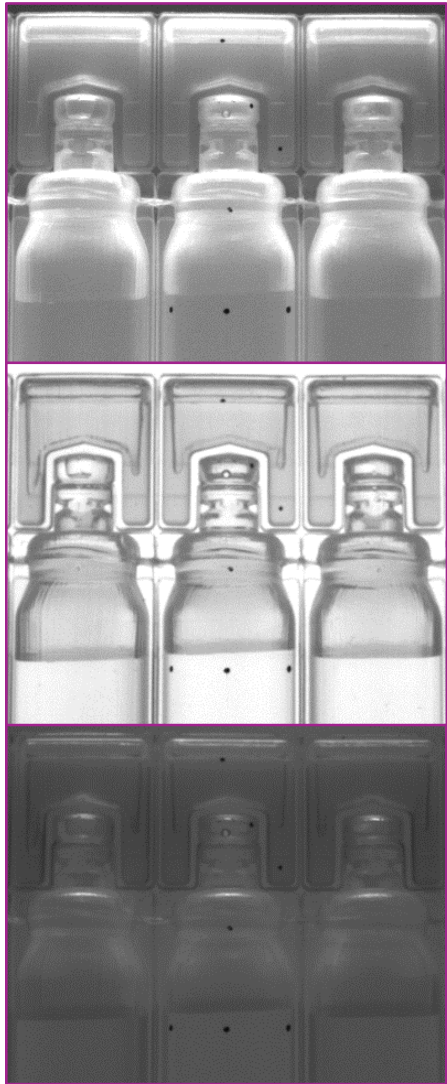
Special illumination

Sidewall inspection



- **MCIP (Multi Colour Image Processing)**
- Advanced illumination set-up
- Image subtraction method
- Optimized evaluation image depending on fault category
- 3Mpx camera resolution

Illumination principle



Characteristics image

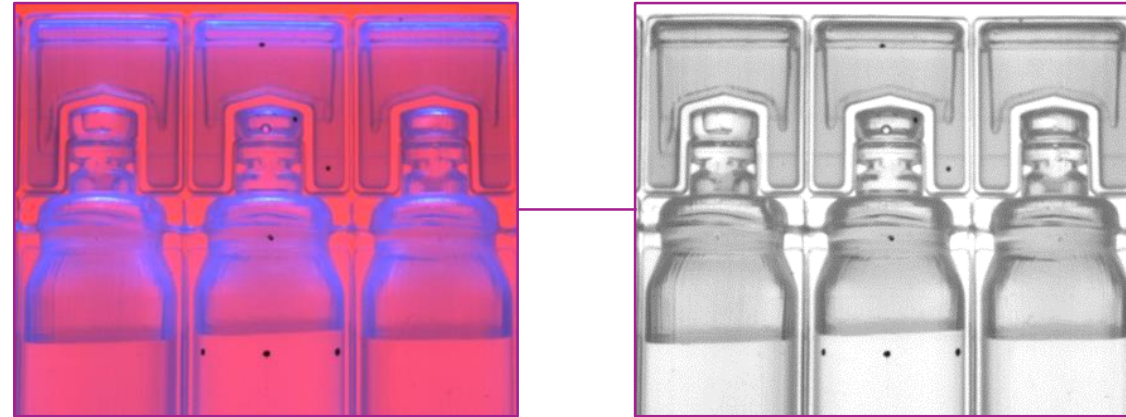
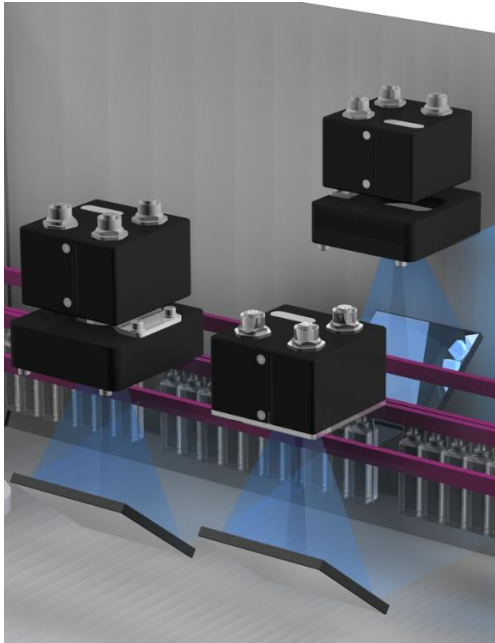


Evaluation



- **Special illumination**
- Detection of opaque greasy contamination

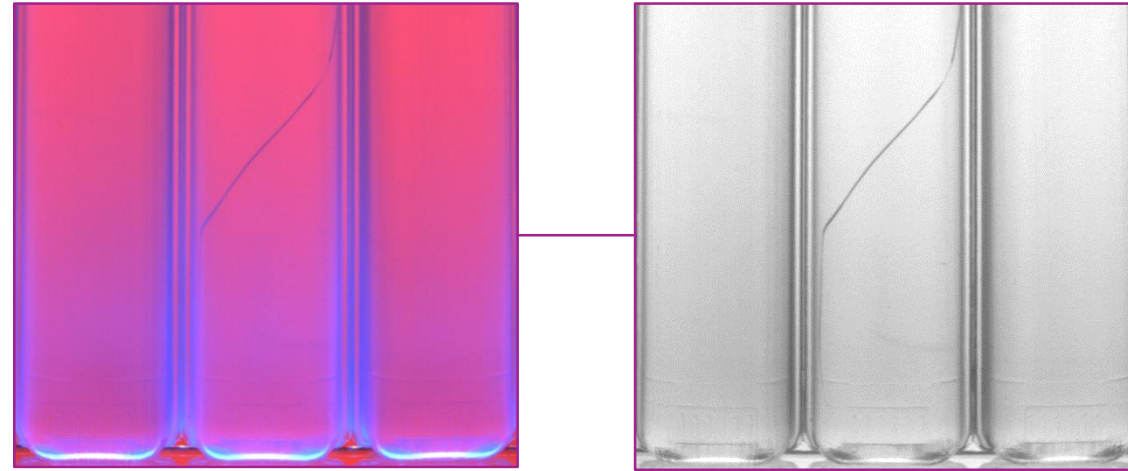
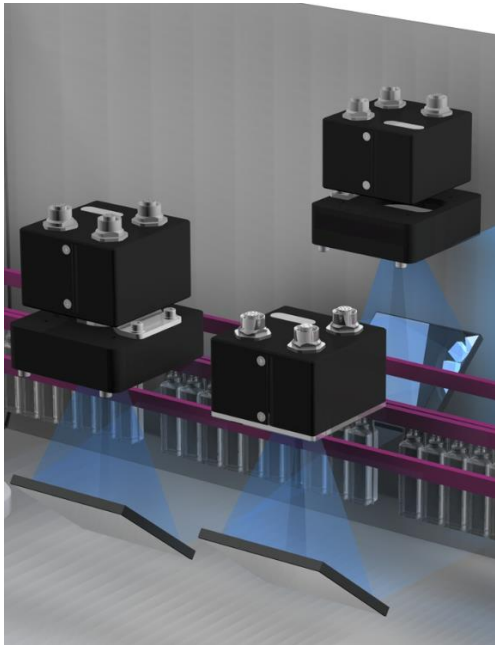
Illumination principle



Upper sidewall inspection

- Closure inspection
- Cosmetic defect detection
- Particle detection
- Fill-level detection

Upper sidewall inspection



Lower sidewall inspection

- Cosmetic defect detection
- Particle detection
- Discoloration detection

Lower sidewall inspection



Body damage
scratch



Fill-level
underfilled / overfilled



Particle
filter material



Black spots
inclusions

Examples of various defects



Forming defects
interrupted connector



Excess material
Lack of material

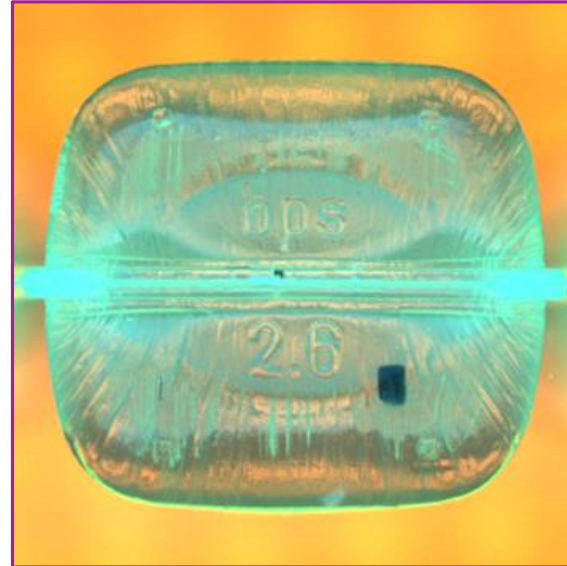
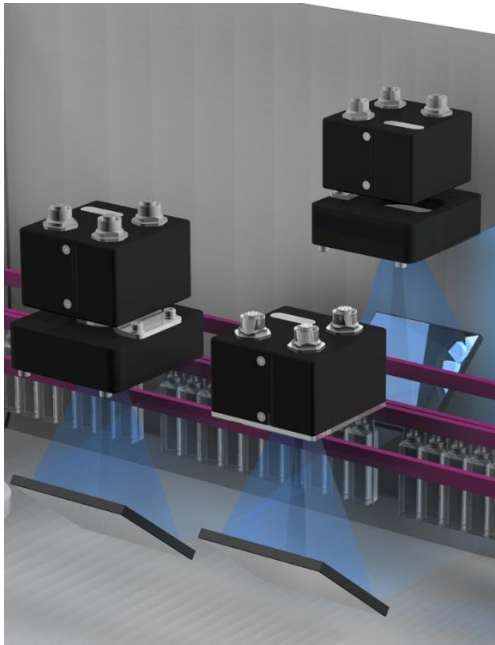


Discolorations
product



Body damage
pinch

Examples of various defects



Base inspection

- Cosmetic defect detection
- Particle detection



Particle
rubber particle

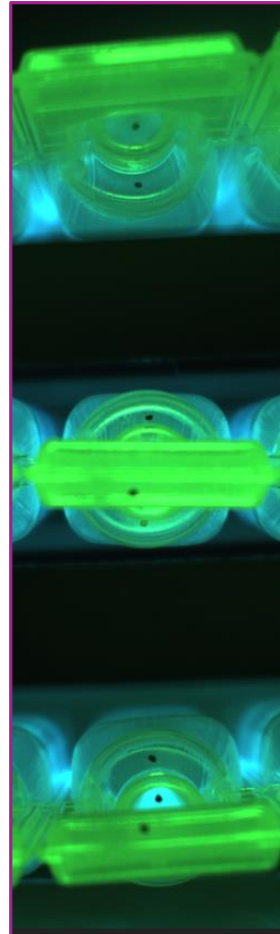
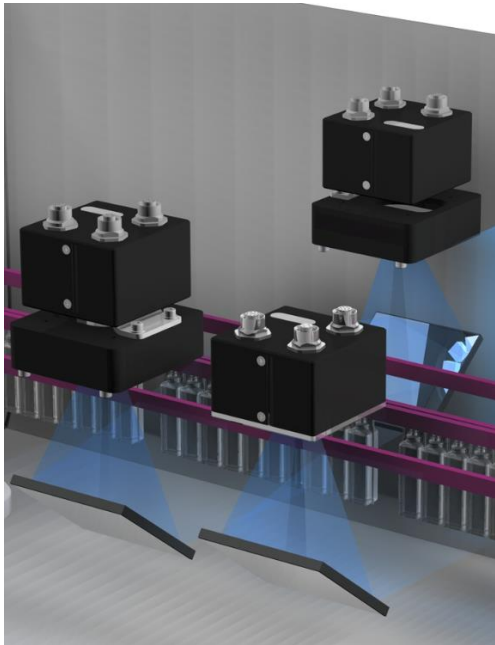


Black spots
inclusions



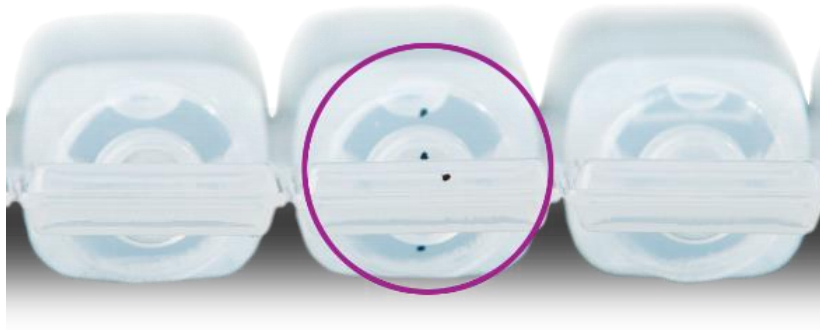
Particle
metal particle

Examples of various defects

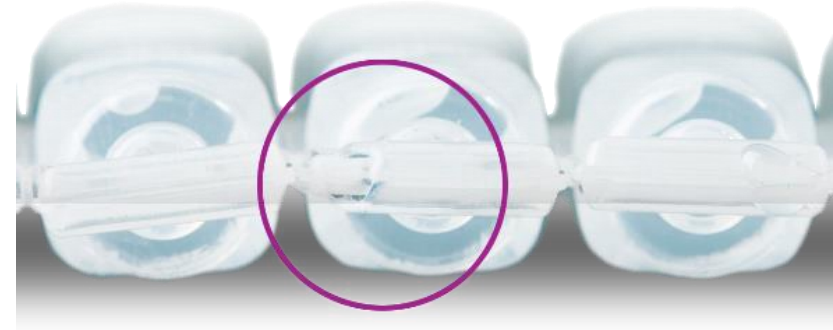


Top-down inspection

- Optomechanical design to eliminate blind spots
- Closure inspection
- Cosmetic defect detection



Black spots
inclusions



Body damage
damaged closure

Examples of various defects

Various automatic rejection systems are available for the rejection of incorrect products.



Rejection

Thank you...

We are glad to get in contact with you!

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