

skan

SKAN ebeam
Your Annex 1 compliant
RTU transfer system with
surface sterilisation



SKAN ebeam for full Annex 1 compliance

The SKAN ebeam is designed for transferring pre-sterilised tubs with RTU components such as syringes, vials and cartridges into high-speed isolator filling lines. The tub surface is sterilised using accelerated electrons (beta radiation) upon transfer to the grade A zone.

In Annex 1, this transfer process is defined as one of the "greatest sources of contamination" (4.10). This is why sterilisation upon transfer is the preferred method of introducing material to grade A areas (8.47).

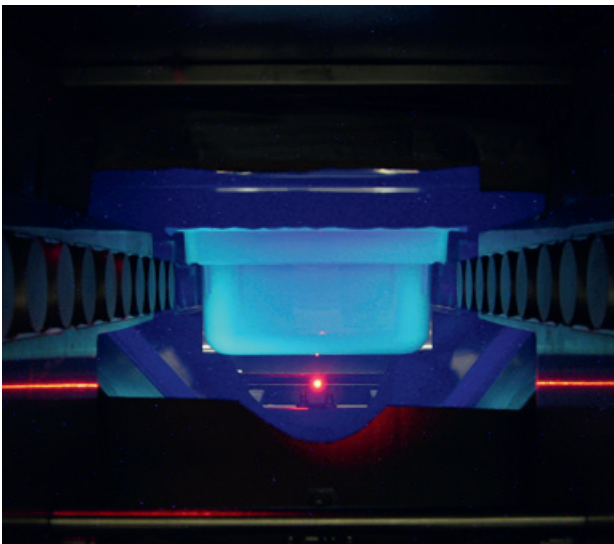
Given these requirements, in-line surface sterilisation with the the ebeam significantly simplifies your contamination control strategy.



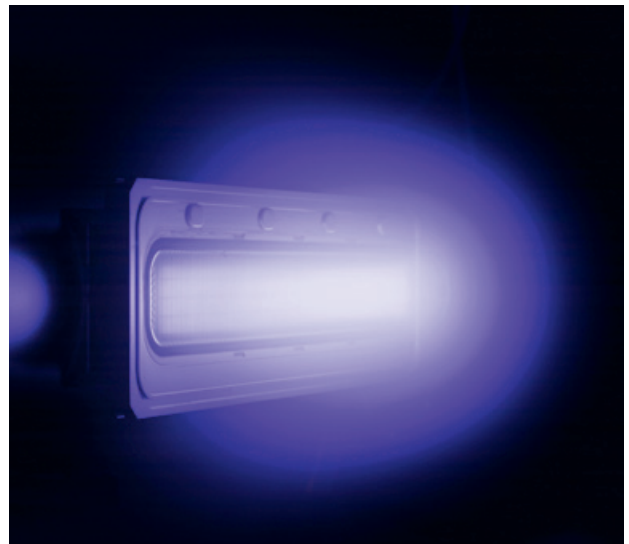
Why ebeam?

If you are looking for an Annex 1 compliant way to transfer RTU components into your isolator filling line, then look no further than ebeam technology. With an ever-increasing number of standards and regulatory requirements in pharmaceutical manufacturing, ebeam is the safest transfer and surface sterilisation solution on the market, and carries the most approvals from relevant authorities.

- Efficient, continuous transfer embedded in a compact design
- High-speed production with up to 6 tubs/min
- Assured tub integrity during the whole transfer process (from grade C to grade A)
- >6-log tub surface sterilisation
- Widespread acceptance by FDA and other inspection authorities
- "No-risk transfer" for full Annex 1 compliance
- Simple qualification and validation
- Maximum Overall Equipment Effectiveness (OEE)
- Low maintenance requirements and costs
- Significant reduction in operating costs



Tub in the emitter zone



Active emitter

How does it work?

Infeed

The process is configured for tubs in single-bag packaging. First, the tub is removed from the bag in front of the tunnel entry, which is a grade C room. (1) It is then placed on a conveyor system which acts as an interface to the ebeam tunnel. (2)

The Tyvek lid remains in place when the tub is moved into the entry section. Once the tub has entered the first airlock, the outer door closes automatically, while the inner door opens. (3) This parallel shutter system guarantees full radiation shielding.

Surface sterilisation

During the main process, the tub is exposed to a radiation dosage of at least 25 kGy on all sides, which is required for safe surface sterilisation.

This process destroys the DNA of all pathogens such as bacteria, fungi, yeast, spores, parasites, and viruses. While killing all living cells, there is no adverse effect on the tub or the RTU components.

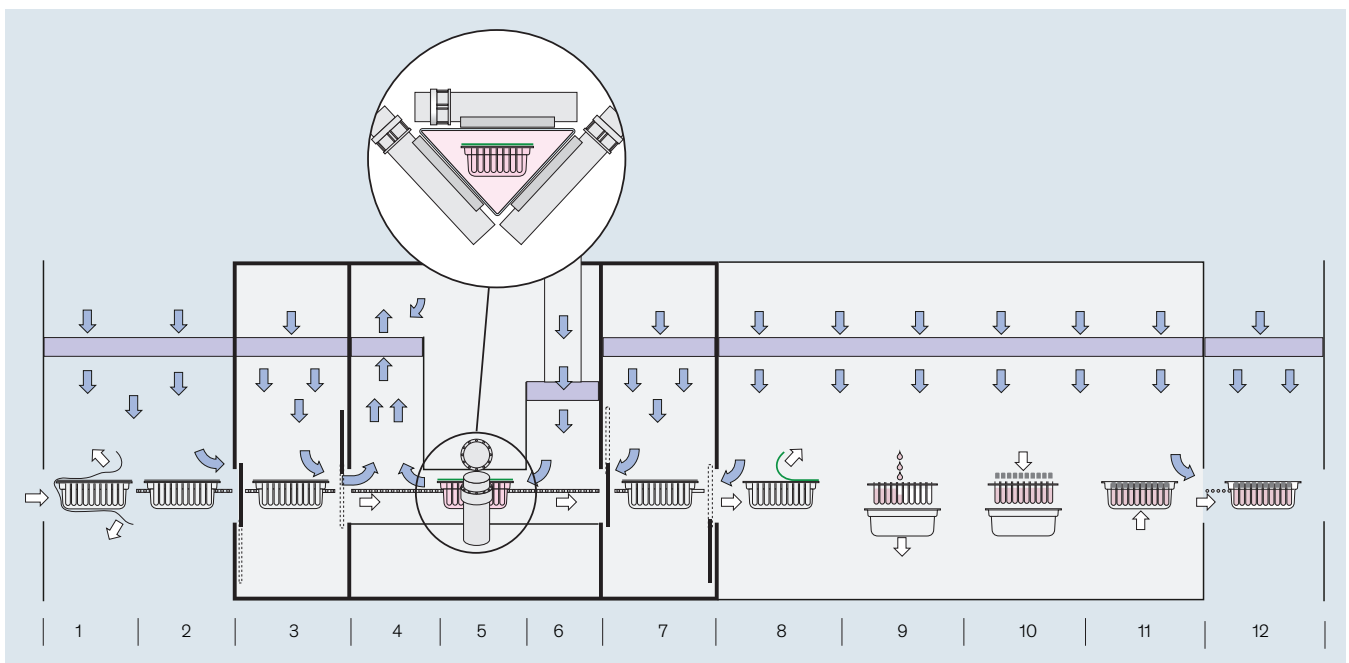
Outfeed

After surface sterilisation, the tub leaves the tunnel through the second airlock into the isolator. (7) This represents a direct transfer from cleanroom class C to class A.

Air handling

The ebeam system has an integrated, advanced air handling system with unidirectional airflows at the inlet points (3, 6, 7) and a defined pressure cascade between the ebeam tunnel, cleanroom and isolator.

Both inlet and outlet air are HEPA-filtered. This guarantees that no particles or contaminated air enter the isolator and surrounding room. Byproducts such as Ozone and NOX are sucked into the exhaust air system. (4)



Specifications

Technical specifications

Dimensions W x H x D + min. 1000 maintenance area both sides	2400x3183 (3000)x1216 mm
Weight	2t/m ²
Construction material	Stainless steel and lead
Certified radiation shielding integrity	< 1µSv/h at 100 mm distance
Power consumption	6-7 kWh/hour in production
Utilities	Power & compressed air
Expected emitter lifetime	> 6'000 h

Automation

SCADA	Including batch report functionality
Software	Factory Talk (Rockwell Automation) Zenon (COPA-DATA)
PLC (GAMP-5 compliant)	Allen Bradley Siemens
HMI	Beckhoff



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