

• PRODUCT BRIEF • 10 MIN READ

ZeroStop®

CONTINUOUS STERILIZATION

A new grammar for sterilization —
continuous where the industry knew
only batch.

• ANNEX 1 COMPLIANT BY DESIGN



ZeroStop® Sterilization

Be Annex 1 Compliant. No more stops and bottle necks in the sterilization phase



No more Autoclave Trolleys

SAVE SPACE.
SIMPLIFY YOUR PROCESS



No more Manual Transfer

AS STRONGLY ENCOURAGED
BY THE NEW ANNEX 1

— Process versatility

Five *sterilization* technologies, *one station.*

ZeroStop® supports the main spectrum of sterilization methods used in pharma — thermal, with steam or water and the breakthrough low-temperature HyPerPure® under deep vacuum.

STERILIZATION TECHNOLOGIES · ZEROSTOP® STATION

- | | | | |
|----|---|--|------------------|
| 01 |  | Saturated steam
Thermal | → NOW CONTINUOUS |
| 02 |  | Air / steam mixture
Thermal | → NOW CONTINUOUS |
| 03 |  | vH₂O₂ HyPerPure® · deep vacuum
Low-temperature · vaporized H ₂ O ₂ | → NOW CONTINUOUS |
| 04 |  | Hot air
Thermal | → NOW CONTINUOUS |
| 05 |  | Superheated water
Thermal | → NOW CONTINUOUS |

AND — COMBO CONFIGURATION

Up to 3 technologies can be *combined* inside the same ZeroStop® station — more versatile, more flexible.

— What ZeroStop® does

From *batch*, to continuous *flow*.

A continuous sterilization station, positioned between the filling line and downstream handling — delivering uninterrupted output where the industry knew only closed-door batches.



01 — INLINE

Between filling
and *downstream*.

02 — UNINTERRUPTED

No *closed-door*
pauses.

03 — STEADY STATE

Output matches
line rate.

— Paradigm shift

Three frames, *one redefinition.*

BEFORE

Yesterday

Closed-door
batches.

Discontinuous output, manual handling, fixed cycle windows.

NOW

With ZeroStop®
Continuous station.

Uninterrupted flow from the sterilizer that previously
worked only as a batch.

RESULT

Outcome
A new category.

Not a faster tunnel — a different paradigm for sterile flow.

— Under the hood

Protected by *international patent.*

ZeroStop® is an exclusive by **De Lama** protected by international patent.



— Operational impact

Leaner *layout*, better *plant*, better *process*.

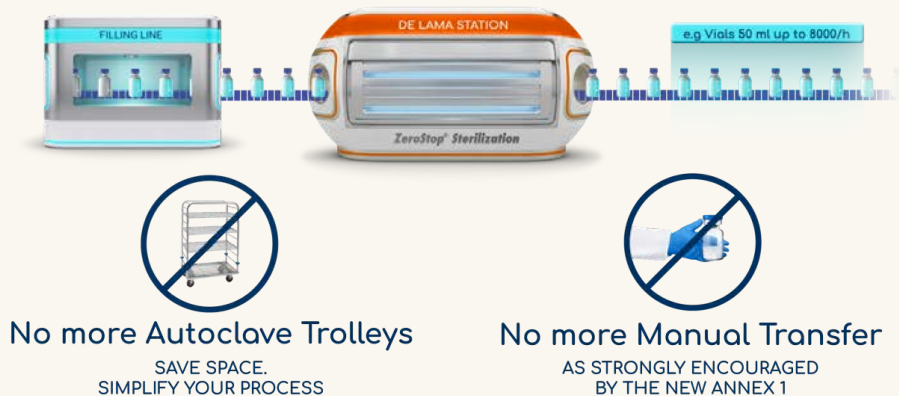
The plant reorganizes around continuous flow — less space consumed, fewer manual steps, a cleaner workflow from sterilization to downstream.

• PLANT-LEVEL REDESIGN, NOT A UNIT SWAP



ZeroStop® Sterilization

Be Annex 1 Compliant. No more stops and bottle necks in the sterilization phase



— Measurable outcomes

Three *directions*, one *simpler plant*.



Floor space

Reduced footprint for sterilization operations inside the plant also for trolleys elimination.



Manual handling

Time lost to manual load and unload operations — eliminated.



Workflow order

Production line organized around continuous flow, end-to-end.

• EU GMP ANNEX 1 • 2023 REVISION

— Regulatory alignment

Annex 1 *compliant* by design.

The new Annex 1 sets the expectation for aseptic processing: minimize manual intervention, automate material flow, and strong push on isolators. ZeroStop® is engineered around exactly these principles.

PRINCIPLE 01

Minimize manual intervention.

PRINCIPLE 02

Implement isolators.

PRINCIPLE 03

Reduce contamination vectors.



— The regulation



EU GMP ANNEX 1 · § 4.3

Restricted Access Barrier Systems (RABS) or isolators are beneficial in assuring required conditions and minimizing microbial contamination associated with direct human interventions in the critical zone.

Their use should be considered in the CCS. Any alternative approaches to the use of RABS or isolators should be justified.

Manufacture of Sterile Medicinal Products · 2023 revision

— In summary, Annex 1 requires

a. Use of *isolators*, wherever possible.

b. Minimize *human intervention* — the primary contamination vector.

DE LAMA — ZEROSTOP®

Hits both outcomes: it *integrates into the filling-line flow* and removes manual load/unload end-to-end.

• EU GMP ANNEX 1 • 2023

— Annex 1 • 01 of 02

Eliminate the *handling* infrastructure.

ZeroStop® removes the trolleys, racks and floor space that batch sterilization required — a cleaner plant, a simpler process.



No more Autoclave *Trolleys*.

SAVE SPACE.
SIMPLIFY YOUR PROCESS.

• EU GMP ANNEX 1 • 2023

— Annex 1 • 02 of 02

Remove the *human hand* from the line.

The new Annex 1 strongly discourages manual handling in aseptic processing. ZeroStop® is designed around this principle — automated end-to-end.

"As strongly encouraged by the new Annex 1."

EU GMP Annex 1 — Manufacture of Sterile Medicinal Products



No more *Manual Transfer*.

AS STRONGLY ENCOURAGED
BY THE NEW ANNEX 1

• A NEW PARADIGM

Not a faster sterilization. *A different category.*

Annex 1 compliant by design — continuous operation where the industry knew only batch.

ZeroStop® Sterilization



► SEE THE VIDEO ON YOUTUBE
youtu.be/oTvyCrEY5NY



◆ DISCOVER ON DE LAMA WEBSITE
delama.it/product/zerostop-continuous-sterilization