

**FULLY  
CONTAINED  
LINES FOR  
OSD FORMS**

**HP**





## HIGH POTENT ISOLATOR DESIGN, FUNCTIONALITY & SAFETY

Nicomac Europe has focused the design of equipment under isolators to safety and technology of machinery. Standardization of transfer valves and containers, and compatibility with upstream and downstream processing can contribute significantly to the selection of a suitable containment strategy, while equipment cleaning and maintenance should also be addressed.

Nicomac Europe supplies, installs and validates complete isolated lines for the production of Oral Solid Dosage Forms, with batch size from 1 kg up to 65 kg with containment level from OEB3 down to OEB5.



4.500m<sup>2</sup>  
of productive site

1.800+  
successful projects

9  
patented systems

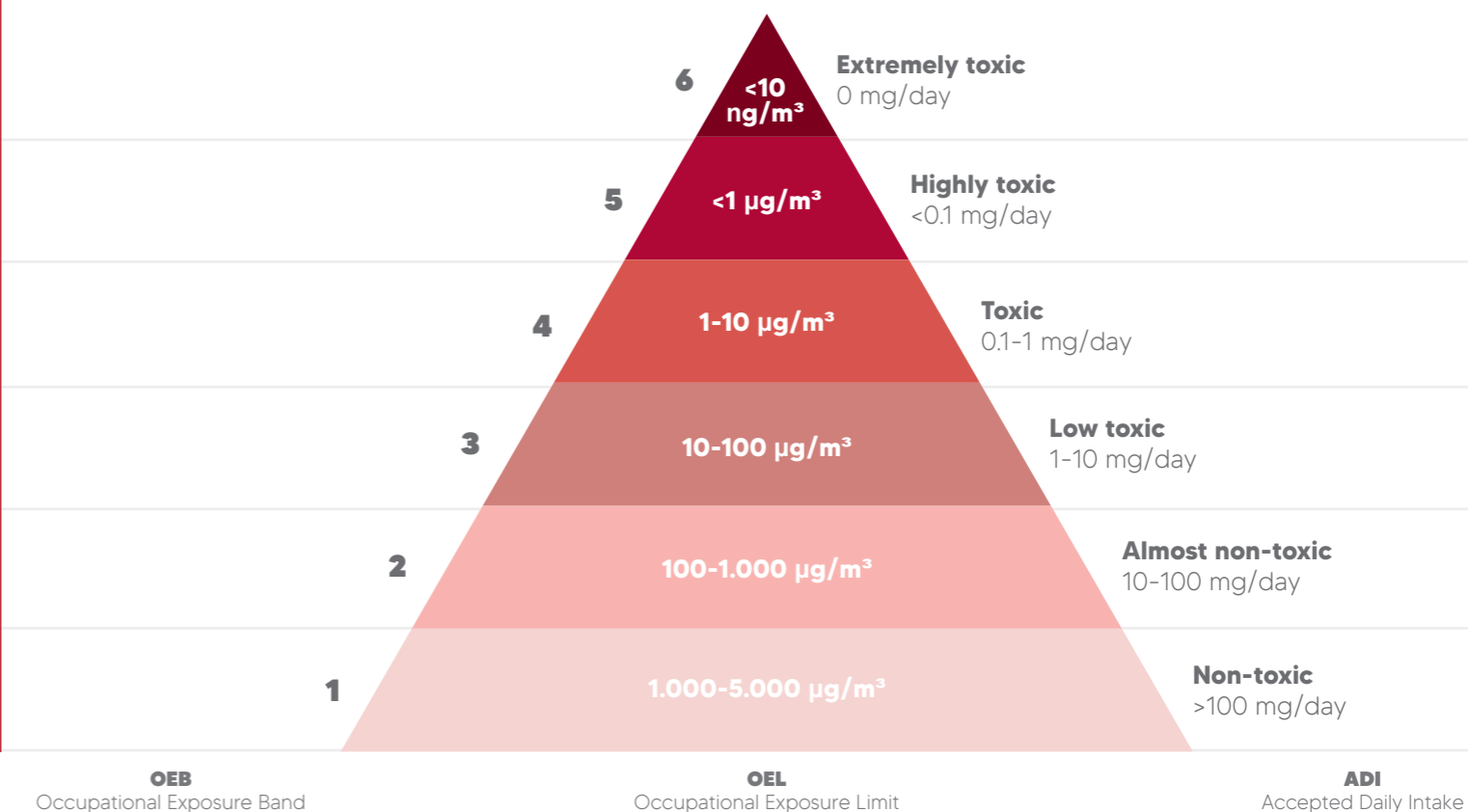
65  
Countries served

15  
new devices and  
novelties

45  
years of experience

Nicomac Europe is one of the leading companies in the international clean room and equipment for oral solid departments. Founded in 1977 in Milan, Italy, in over half a century successfully realized over 1800 projects in 65 Countries in the world, supplying clean rooms, coating systems and granulators that can also be under isolator.

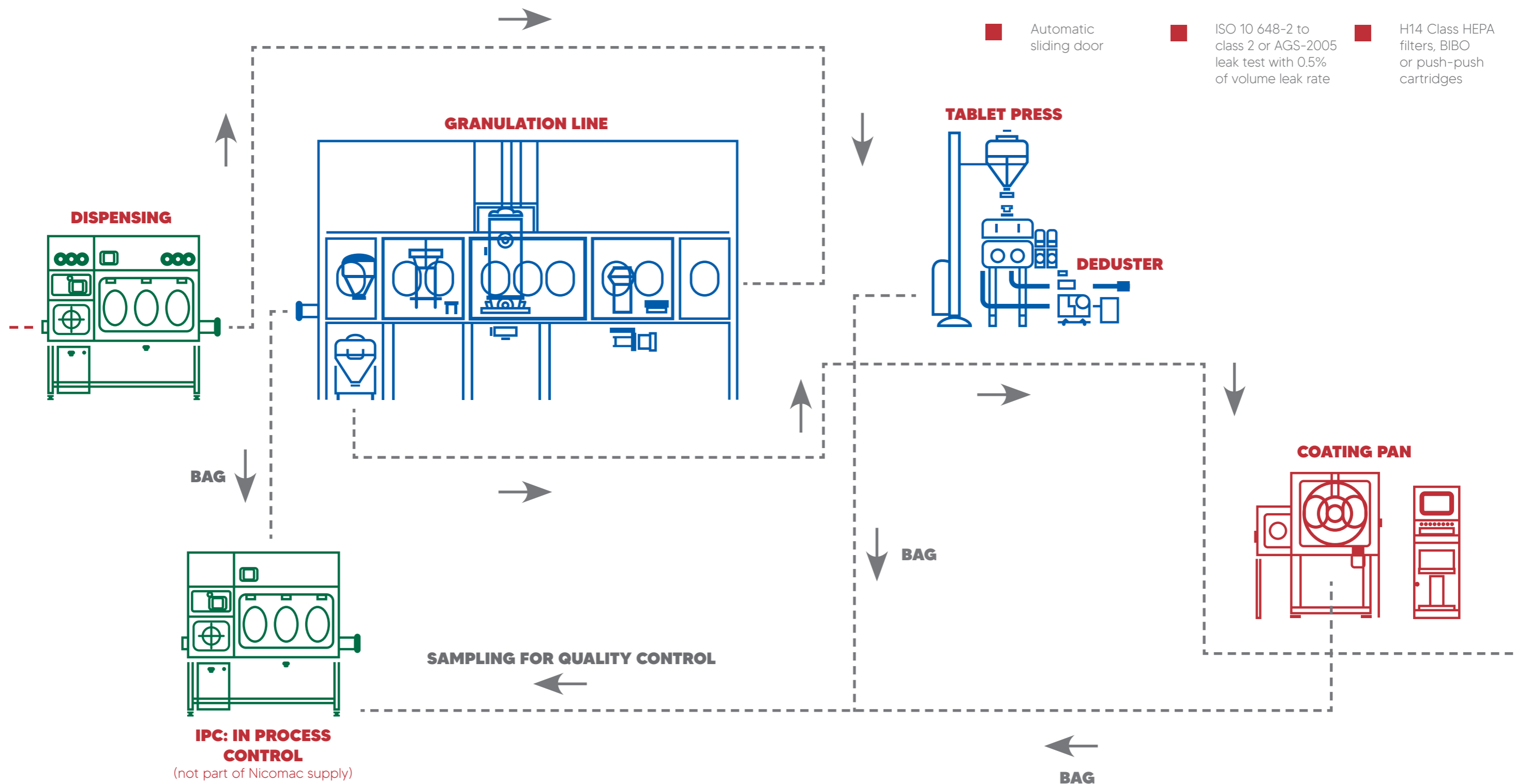
The excellence in quality and products, along with the support of an expert and qualified team, are the foundation of the results obtained by Nicomac Europe and the satisfaction of its clients, many of them FDA/EMA approved.



## TECHNICAL FEATURES

The isolators design ensure the correct operational ergonomics, efficiency and safety of the process. The construction of a mockup during early design phase gives the possibility to guarantee the best isolator's design.

- Full stainless construction design
- Ergonomic study, high level finishing for best cleaning
- FDA/EMA approved materials
- Multiple transfer systems available
- CFR21 Part 11 compliant control system
- Small dispensing room, washing bin and room
- Controlled constant negative pressure
- Down to CTP<0.1 µg/m<sup>3</sup> TWA (OEB5)
- Automatic sliding door
- ISO 10 648-2 to class 2 or AGS-2005 leak test with 0.5% of volume leak rate
- H14 Class HEPA filters, BIBO or push-push cartridges





Dedicated isolator units are required for preliminary and verification activities in the OSD forms manufacturing. Dispensing isolator allows proper weighting of HPAPI with excipients according to required formulation.

IPC isolator hosts the necessary instrumentations for in process testing according to quality control program. Sampling devices ensure the possibility to extract product samples as process needs.

## DISPENSING QC-SAMPLING



## WASHING SYSTEM (BIN & COMPONENTS)

For cleaning purposes, decision should be made regarding whether in place cleaning is implemented or not, which cleaning materials will be used and the type for cleaning methods that will be employed. While clean-in-place methods rely on automatic procedures, which requires no manual intervention, wash-in-place techniques necessitate some manual involvement. Ergonomics is yet another factor to be considered: accessibility, availability to make necessary equipment adjustments, and the ease of equipment cleaning.





## GRANULATION LINES

Compact granulation line in a single isolator: with automatic sliding doors, built-in lights and rails for container handling.

All the machines have technical part outside the isolator chamber, for an easier maintenance and better cleaning.

### THE LINE INCLUDES:

- Pre-chamber with small dispensing zone
- High-Shear Mixer
- Fluid Bed Dryer
- Calibrator
- Blender
- Unloading with continuous liner or 50 L BIN



### GRANULATION LINE FEATURES:

- Pre-chamber and main chamber
- Fluid Bed Dryer
- Control system CFR 21 Part 11 for monitoring and controlling
- Stainless steel pleated filters
- High Shear Mixer
- Material exit: endless liner, split butterfly valve or RTP
- Ergonomic internal doors and safety barrier
- Comill and blender
- Pneumatic transfer from FBD container to Comill and from Comill to blender









## COATING EQUIPMENT

Nicomac Europe SWC type coating machines are designed to be easily integrated with a containment system for safe loading and unloading of tablets. The design ensures full integration with control system, semi-automatic operations and easy washing procedure. The exhaust fan of the coating machine is also used to create the negative pressure of the isolator.



## CAPSULE FILLING MACHINE

Capsule filling machine requires special containment due to its particular operation. The isolator is typically a "hat" on the machine basement and the control systems is fully integrated. Capsules discharge line depends on machine productivity and direct exit toward deduster and metal checker are suggested.



## TABLET PRESS

Tablet press turret is fully enclosed in an isolator chamber designed on top of the machine. Utilities of the tablet press are also HEPA filtered and their control is integrated in the isolator pressure control system. WIP is available assuring full product removal.





## TRANSFER SYSTEMS

Attention to detail is of importance for successful transfer technology. At the heart of every successful program is a well-executed material transfer technology and the key to successfully commercialize high-potency and high performance drugs with contract-manufacturing partners.

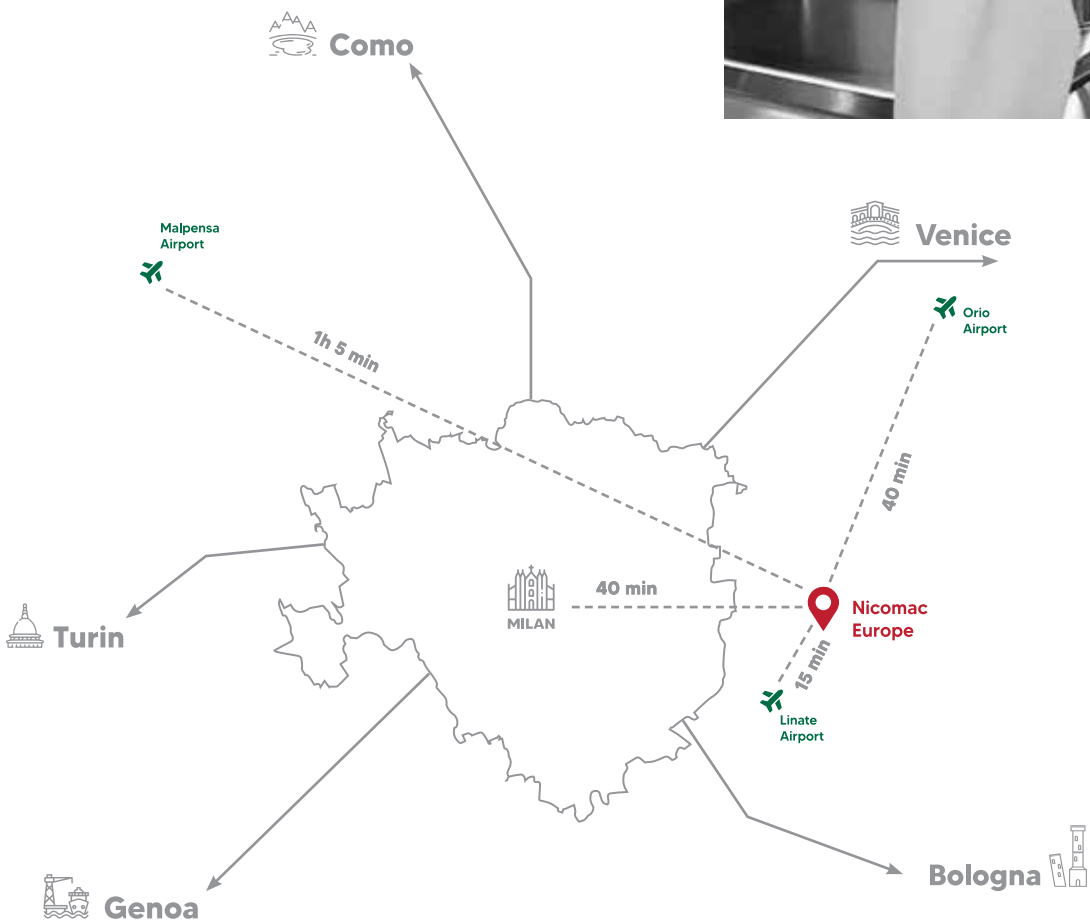


## HANDLING SYSTEMS


- Lifting columns
- IBC or BINS
- Vacuum Transfer Systems







## GET IN TOUCH

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