



## Welcome to the presentation of **Lytzen**



**The heat treatment specialist!**

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Warsaw, 7-9/11/12

AR Pharma

Helmut Müller



## Lytzen History

**Danish company in 1947,  
Specialized in ovens in the fifties,  
Specialized in pharmaceutical ovens in  
the seventies,  
Was the first company to comply to the  
FDA class 100**



## Lytzen Philosophy

Never to compromise on our high level of quality in every detail.

## Lytzen customers

Pharmaceutical industries all over the world, like Pfizer, GSK, Merck, Novartis, Astra Zeneca, Hoffmann LaRoche.



## Products

**Dry Heat Sterilizers ISO Class 5 & ISO Class 7  
Granulate Dryer / Tray Dryer**



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## Dry Heat Sterilizer application area

**Batch oven, working temperature 250° C or  
Empty vials, ampoules, injection bottles, af  
Closed bottles with low aqueous liquids or powder medicin,  
Other sterilisationpurposes, e.g. clean room furnitures,  
Small- mid size scale production, R&D, Biotech, large hospital pharmacies.**





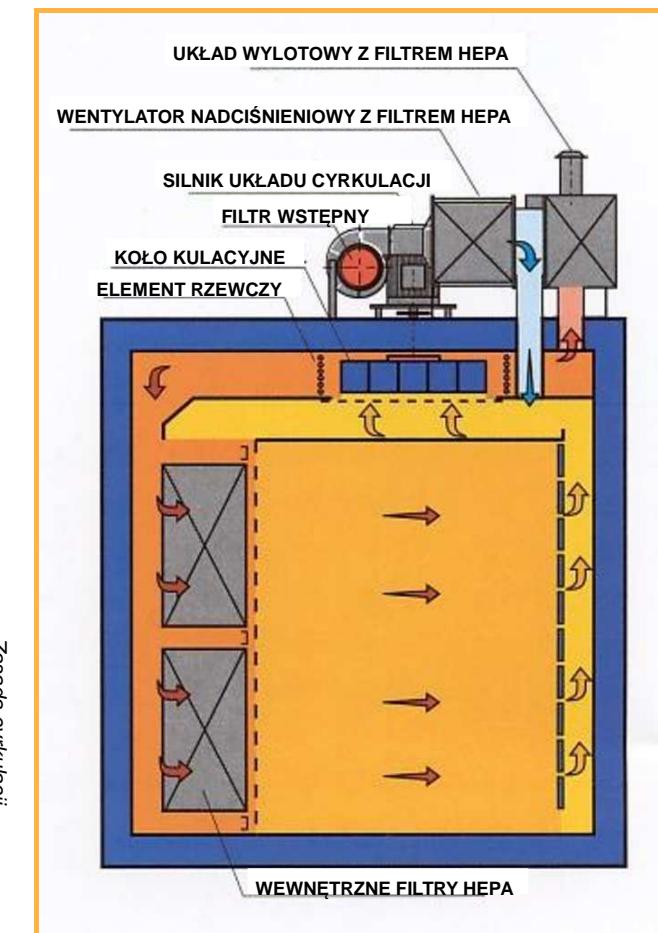
## Principle of Dry Heat Sterilizer

Forced convection principle with heat transmission to load.

Cheap and environmental friendly process.

Recirculation air / Damper on outlet.

Saving energy during cycle.





## Lytzen fulfils the ISO Class 5 standard during the entire cycle

**ISO Class 5= 3520 part./m<sup>3</sup>, size 0.5µm  
(100 part./cubic foot)**

**Particle number is far below acceptance criteria – inclusive the critical heating and cooling phases.**

## SUPERIOR CHAMBER SEALING

**Lytzen developed filter-suspension system,  
Fully welded chamber,  
Air seal for fan shaft,  
Double door gasket,  
HEPA - Filter Air inlet and outlet**

LYTZEN		TEST REPORT		DATE : 05.12.15		
PARTICLE COUNT				SIGN.: HAB /		
CUSTOMER :						
ORDER NO. : A051120 (a) MACHINE TYPE : H1F/1650						
MEASURING EQUIPMENT						
TYPE : ROYCO PORTABLE		SERIAL NO:9109P510	VALID:Apr2006			
CRITERIA						
ISO 14644-1						
METHOD STATEMENT						
EACH MEASUREMENT IS COLLECTED DURING A SAMPLETIME OF 5 MINUTES WITH A TOTAL FLOW OF 1 CUBICFOOT (CuFt) TEMPERATURE READINGS ARE ONLY GUIDANCE VALUES.						
MEASURING RESULTS						
D 16:12	52	0.5 µM				
H 16:18	153	0				
16:23	177	1				
16:28	212	0				
16:33	242	0				
16:38	258	0				
16:43	263	2				
16:48	266	10				
16:53	268	2				
16:58	268	0				
17:03	269	0				
S 17:14	271	0				
17:19	271	0				
17:24	271	1				
17:29	272	4				
17:34	272	0				
C 17:39	272	1				
17:44	272	2				
17:49	268	1				
17:54	248	0				
18:00	205	0				
18:05	166	6				
18:10	142	1				
18:15	116	4				
18:20	98	6				
18:25	92	0				
18:30	77	10				
18:35	66	1				
18:40	57	4				
18:45	60	1				
E 18:51	53	0				
18:56	48	1				
AVERAGE COUNTS						
PARTICLE SIZE 0.5 µM = 1.8 [PARTICLES/SAMPLE]						
INDEXES						
D=DRYING	H=HEATING	S=STERILIZING	C=COOLING	E=END		
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7.2.05



**Customized chamber sizes**  
size depends on customers demands

**Homogeneous temperature distribution**  
**Lytzen Standard:** Max  $\Delta 5^\circ \text{C}$  inside chamber,  
**Fixed temperature distribution plate,** no  
**baffles needed,**  
**Easy and fast validation.**





**Thank you for your attention!**

**Questions? Please visit us at ARPHARMA Stand for more information**