

WUJIANG PAILIXIN METAL PRODUCT CO, LTD

吴江派利欣金属制品有限公司

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**EO-Sterilization Batch Report(环氧乙烷灭菌批记录)**

Date: 2020/09/23

QR NO. QR20247


Client: Painful Pleasure

Add: 7410 Coca Dr. Unit 107, Hanover MD 21076, USA

Contact: Marc

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General Information			
Sterilization No.		200901-1	
Customer name		PAINFUL PLEASURE	
Brand name		Peak	
Date of reception		2020.09.01	
Temperature of Environment		50°C	
Product name	Product type	Product Lot#	Cases
STAINLESS STEEL PIN WITH TUBE	1RL 0.25MM etc	200901	13CTNS
PLASTIC TUBE		200901	10CTNS
PLASTIC TRAY			5CTNS
Sterilization process data			
Preconditioning time		1.5-2.5hrs	
Date of sterilization		2020.09.01	
Station number		7	
Batch number		200901	
Aeration time		7 Days	
Results of Physical process control			
The physical Acceptance criteria of the preconditioning the cycl and the aeration were in compliance with the validated specifications of cycle no.: <u>GBS</u>			
Microbiological process data			
The microbiological process control with biological indicators has been performed according to the BI sterility test sop(032005)			
No of biological indicators indicators 19 per chamber load.		BeiJin Four Ring Medical,Lot No.20170203	
Date of incubation		2020.09.01	
Incubation conditions		7 Days 37°C	
Result of microbiological process control			
[ ]No growth from Bacillus subtilis has been detected			
Remarks			
QA Approval			
Date of release		Signature of QA	
2020.09.01			

We hereby certify that the above mentioned goods(as described by the client)have been sterilized by "Ethylene Oxide".