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1.?? ?????? ??????? ?????????? "ASTM F2338 ??????????? ?? ????? ?????????? ??  
?????????????? ?? ??????????? ?? ?????? ? ?????????? ?? ??????? ?? ??????????? ?? ??????",  
?????????? ?? ??????????? ?? ?????????? ?? ?????????? ?? ?????????? ?? ?????????? ??, ? ???????????????  
????????? ?? ?????????? ?? ?????????? ?? ?????????? ?? ???????, ?????????????? ?? ???,  
????? ?? ?????????? ?? ?????? ?? ?????????? 1 ??????, ? ?????????? ?? ????? ?? ??? ?? ??????  
????????? ?? ??????? ?? ??????? ??.

2.?? ?????????? <1207.1> PACKAGE INTEGRITY TESTING IN THE PRODUCT LIFE CYCLE-TEST METHOD SELECTION AND VALIDATION, "Technical Guidelines for Sealability Research of Chemical Drug Injection Packaging System (Trial)", "Technical Requirements for Quality and Efficacy Consistency Evaluation of Chemical Drug Injection Generic Drugs ?, ?????????????? ?????? ? ?????? ?????? ?????????? ?????????? ?????? ??????????.

3.????????????????? ??????????? ?? ??????? ??????????, ?????????????? ? ??????????????  
????????????????? (IQ/OQ/PQ).  
4.????????????????? ????????, ?????????????? ?????? ?????????????? ?????? ??? ??????  
????????????? ?????? ???????, ??????? ?? ????? ?????????? ?????? ??????????.

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1.???? ??????? ?????????????? ?? ?????????? ?? ?????????????? ?????? (????????? ??????, ??????????????  
????????????? FDA ? ??????????), ? ?????????????? ?????? ?????? ??? ?????? ?????? ??????  
?????????.

2.????????????? ?????? ?????? ???????????, ??? ?????? ?????? ?????????? ?????? 0,5 ??????,  
??? ?????? ?????????? ?????????? ?????? ?????? ?? ?????.

3.????????????? ?????????? ASTM F2338, ?????????? ? ?????????? ?????????? ?????????? ??????  
????????? ?????????? ?????????? ?????????? ?????????? ?????????? ? ?????????? ??????????

4 ?????????????? ?????????? ?????????? ?????????? ?????????? ?????????? 0+-50°C

5.????????????? ?????????? ASTM F2338, ?????????? ?????????????? ??????????, ????  
????????????? ?????????????? ?????????? ?????????? ??????????????, ? ?????? ?????????? ??????????  
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6.1-????????? ?????????? ???? ?????????????? ??????, ??????? ??????????? ?? ??? T5CPU,  
????????? ???????????

7.?????????? ??????????????? ?????????? ??????, ?? ????? ??????? ??????????? ???????????, ? ??????  
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 1.????????????? ?????????????? ?????????????? ?????????? ?????????????? ?????????? GMP ? ??????????  
 ?????????? US FDA 21 CFR PART 11 ?? ?????????? ?????????? ? ?????????????? ??????????  
 2.????????????? ?????????? ?????????? ?????????????? ??????, ?????????????? ??????????  
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 3.????????? ?????? ?????????? ?????????? ?????????? ? ?????????? ?????? ??? ? ??????????????????  
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 ?????????? ?????? ??????????  
 4.????????????? ?????? ?????????? , ?????????? ?????? ?????????? ?????? ?????? ???  
 ?????????? ?????????? ?????? , ??? ?????????? ?????????? ?????? ??????????  
 5.????? ?????????? ?????????????? ?????????????? ?????? ?????????? ??????????  
 ?????????? ? ?????????????? ? ??? ?????? ?????? ??? USB.

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 1.????????????? ? ?????????? ?????????????? ?????????????? ?????????????? ?????????????? ???  
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 ?????? , ?????? ?????????? ??????????  
 2.????????????? ? ?????????? ?????? LenoxLASER ??? ?????????????? ??? ?  
 ?????????? ?????????? ?????? .  
 3.????? ?????????????? ?????????? ?????????? , ?? ??? ?????? ?????????? ?????? ??????????  
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 4.????? ?????????? ?????????? ?????? ?????? ?????????? ?????? ? ?????? ?????? ?????? ???  
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 ASTM F2338. ?????? ?? ?????? ?????? ?????? ?????? ?????????? ?????????? , ??????????????  
 ?????? ?????? . ?? ?????? ?????? ?????? ?????? ?????? ?????? ?????? ? ?????????? ?  
 ?????? , ?????? ?????????? ?????? ?????? ?????? ?????? ? ?????? (?????????????)  
 ?????? ?????????? ?????? ?????? ? ?????? , ??? ??? ?????? ?????? ?????? ,  
 ?????????? ?????? ? ?????? , ??? ??? ?????? ?????? ?????? ),  
 ?????????? ?????? ?????? ?????? ?????? ?????? ?????? ?????? ?????? ?????????? ??????.  
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 ?????? ?????? ?????? ?????? (?? ??? ?????? ?????? ?????? ??????) ? ?????? ??????  
 ?????????? ?????? . ??? ??? ?????? ?????? ?????? ?????? ?????? , ??? ??????  
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????? ????????	????? ?????? ?????? , ?????? ?????? ?????? (?????????)
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?????? ?????????????? ??????? ????????	???????????????? ?? ???, ??????? ? ??????
?????? ?????????????? ??????? ????????	1?m 0.009sccm ?1.5×10-5Pa.m3/s
?????? ??????????????	0.2?m
????????????????(???????????)	1?m????????????? ?????????? ???????
?????? ??????????????	30???
????? ?????????????????? ????????	350?? (L) × 300?? (W) × 360?? (H)
?????? ????????	AC100V?240V, 50/60Hz
????????? ????????	????????? ??????? 100W, ??????? ?????????? ??????? 200W
???????	????? 25 ??
???	1 ????????????, 1 ?????????? ??????, 2 ?????????? ????????????????
????????????? ????????	1 ????????????, 1 ?????????? ??????, 2 ?????????? ????????????????
????? ????????	????????????????? ?????????????????????? ??????????????- ????????? ?????? (?????????), ?????????????????? ??????? (?????), ????????? ?????????????? ???????

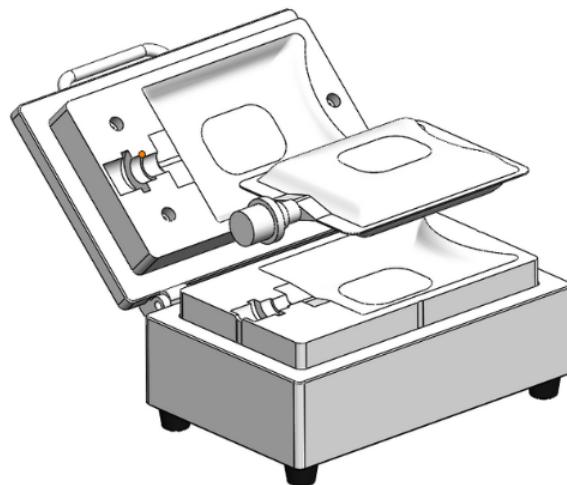
????????? ???????	???????	?????????	???-??	?????? 1	?????? 2
?????? ??????????	?????? ?????? (500 ?? ??? ??????)	304	1 ????????	?????? ?????????? ???????? ?????? 6061, ?????????? ???? MiSUMi (??????), ????????? ?????? ?????? ????? elesa (??????), ?????????? ????????? ?????? ????? SMC (??????), ?????????? ????? Hansheng (??????).	????? ????????????? PTI, ATC, ????? ?????????????
?????? ??????????	?????? ?????? (500 ?? ??? ??????)	304	1 ????????		
?????? ??????????	?????? ?????? (500 ?? ??? ??????)	?????????	1 ????????		
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????????????? ???????. ?????? ?????? ?????? ?????? ?????? ? ?????????????? ??? ??????  
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1. ????????????
2. ?????????? ????????



????????????? 1 - ??????? ?? ?????????? ??????? ??????





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