

DATA SHEET

MDSAP & MDL Number: 112619 & 510(k) Number: K240774
Indonesia Imported Medical Device Registration Certificate

Pen Injector

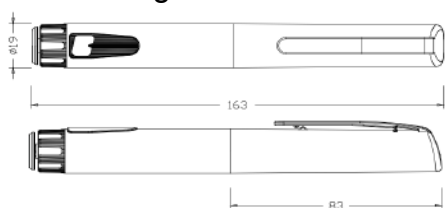
Specification	Technical Data Sheet
Product Name	Pen Injector
Size	163*19mm
Product Weight	35g
Injection Dose Range	0.0075~1.0mL
Method of Use	Install Cartridge→Install the needle→ Perform safety test→ Set the dose→ Injection
Audible Feedback	Audible feedback during dose adjustment
Window	Easy to identify the state of use
Injection Resistance	< 20N
Compatible with 3mL Cartridge	Cartridge compliant with ISO 11608-3:2022 standard
Compatible Needle	Needle compliant with ISO 11608-2 standard
Storage Temperature	Without drug solution: Store at room temperature. With drug solution: Store according to the storage temperature requirements of the drug solution.
Shelf Life	5 years
Batch No.	LOT is shown on outer box label

ISO 11608-1 Test Items	Test Content
Cool Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $5\pm 3^{\circ}\text{C}$)
Standard Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $23\pm 5^{\circ}\text{C}$; Humidity: $50\pm 25\%\text{RH}$)
Warm Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 4 h in the atmosphere(Temperature: $40\pm 2^{\circ}\text{C}$; Humidity: $50\pm 10\%\text{RH}$)
Final-dose Accuracy	Being tested to confirm it delivers the full final dose accurately
Life-cycle Testing	Repeat pressing 4,500 times to test the product's dose accuracy under standard conditions.
Free Fall Reliability Testing	Falling down to the steel plate from height of one meter
Dry-Heat Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 96 h in the atmosphere(Temperature: $70\pm 2^{\circ}\text{C}$; Humidity: $50\pm 10\%\text{RH}$)
Freezing Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 96 h in the atmosphere(Temperature: $-40\pm 3^{\circ}\text{C}$)
Damp-heat Atmosphere Reliability Testing	Being placed in a test chamber to precondition for at least 96 h in the atmosphere(Temperature: $40\pm 2^{\circ}\text{C}$; Humidity: $93\pm 5\%\text{RH}$)
Cycle Testing	Being placed in a test chamber to precondition for 6 cycles(lower temperrature of $(5\pm 3)^{\circ}\text{C}$, upper temperrature of $(55\pm 2)^{\circ}\text{C}$ and $(50\pm 25)\%\text{RH}$)
Vibration Atmosphere Reliability Testing	Reliability testing conducted after vibration according to the IEC 60068-2-6 standard
Transport Testing	Transportation validation conducted according to the standard shipping test method ASTM D4169

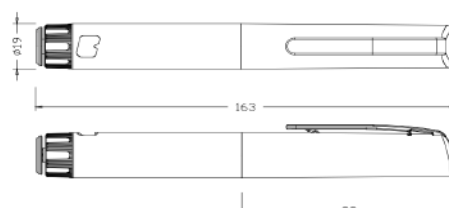
Component Name	Materials
Pen Injector Body	ABS
Pen Injector Cap	ABS
Reservoir	PC
Viewing Window	PC
Dose Adjustment Knob	ABS
Injection Button	POM

Packaging	Technical Data Sheet	Inner Dimensions of the Outer Carton	Picture
NEST Pen Injector	Big Box Package, 1 pc/box, 100 pcs/case	395*350*350	
NEST Pen Injector	Small Box Package, 1 pc/box, 100 pcs/case	385*300*345	
NEST Pen Injector	Blister Package, 1 pc/box, 200 pcs/case	555*285*370	

Technical Drawing



With Dosage Display Window Cover



Without Dosage Display Window Cover