

Factory Information

iRemedy has partnered with one of the largest FDA certified factories in China. They were established in 1999 and the facility is 600 acres with roughly 1,100 employees. During the FDA QSR 820 audit process there were zero defects found. We are actively producing large volume of sterile, disposable needles and syringes. We have 100% of their production allocated to us until April of 2021.

Technical Data

Disposable Sterile Syringe – 1ml, 3ml, 5ml

- Dispensing Syringe: A dispensing syringe allows for the controlled and precise flow of liquid. The dispensing syringe is used to inject medications or other liquids into body tissues. Manual syringes consist of a barrel, stopper, and plunger.
- Dispensing syringes comply with Title 21 Code of Federal Regulations (CFR) 880.5860 and follow International Standards Organization (ISO) 7886-1:2017 or ISO 7886-1:1993
- Calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle
- Heavy duty barrel - The barrel has a scale showing the capacity of the syringe with markings in either ml or cc.
- Stopper - The stopper maintains the fluid in the barrel between the syringe nozzle and the plunger
- Plunger - The plunger is used to aspirate and inject fluids into and out of the syringe
- Disposable, sterile individually wrapped packaging.
- Luer lock to accept luer hub applicator (e.g. needle)





Disposable Hypodermic Needle – 21g, 23g, 25g (1" or 1.5")

- Hypodermic Needle: a slender, hollow instrument for introducing material into the body parenterally.
- Produced in compliance with applicable 21 CFR 880.5570 requirements, OSHA Needlestick Safety and Prevention Act (as applicable) and follow applicable International Standards Organization (ISO) for non-clinical testing such as physical, mechanical & chemical (e.g. 7886 or 7864 or 9626 etc..), or sterile barrier packaging testing (e.g. ASTM standards) or biocompatibility testing as per ISO 1099, as applicable.
- Disposable
- Luer hub to attach to luer lock syringe
- Sterile individually wrapped packaging



Certification Documents

FDA 510k's for the facility and products available for prospects

Sterilization reports available per shipment

SGS certification documents available per shipment

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