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C E R T I F I C A T E

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/172-2020

according to Annex V of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned firm production quality system has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex V of the Directive 93/42/EEC on Medical Devices.

MTIC Intercert certifies that the production quality system conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

JMI SYRINGES & MEDICAL DEVICES LIMITED

Head office: Unique Heights, (Level-11), 117, Kazi Nazrul Islam Avenue, Ramna,
Dhaka-1217, BANGLADESH

Factory: Noapara, Chauddagam, Cumilla-3550, BANGLADESH

DEVICE/S:

- ✓ Sterile, single use, auto-disable (AD) hypodermic syringe;
- ✓ Sterile, single use, hypodermic disposable syringe (DS);
- ✓ Sterile, single use, IV cannula;

MODEL/S:

see list of all models in annex 1

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This certificate is also composed by n. 1 annex made of 3 pages.



Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



C E R T I F I C A T E

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Sterile, single use, auto-disable (AD) hypodermic syringe

- ✓ FP6001 0.05 ml with fixed hypodermic needle 27G x ½" (0.40 mm x 12.5 mm)
- ✓ FP6213 0.1 ml with fixed hypodermic needle 27G x ½" (0.40 mm x 12.5 mm)
- ✓ FP6002 0.5 ml fixed hypodermic needle 23G x 1" (0.60 mm x 25 mm)
- ✓ FP6194 0.5 ml Unibody with fixed hypodermic needle 23G x 1" (0.60 mm x 25 mm)
- ✓ FP6003 1 ml with fixed hypodermic needle 22G x 1" (0.70 mm x 25 mm)
- ✓ FP6004 3 ml, with fixed hypodermic needle 23G x 1" (0.60 mm x 25 mm)
- ✓ FP6005 5 ml, with fixed hypodermic needle 23G x 1" (0.60 mm x 25 mm)
- ✓ FP6006 10 ml, with fixed hypodermic needle 21G x 1½" (0.80 mm x 32 mm)

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Sterile, single use, hypodermic disposable syringe (DS)

✓ FP6007	1ml Luer Slip with Hypodermic Needle 26G x ½" (0.45 mm x 12.5 mm)
✓ FP6076	3ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6010	3ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6241	3ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6009	3ml Luer Slip with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6077	5ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6012	5ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6242	5ml Luer Lock with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6011	5ml Luer Slip with Hypodermic Needle 23G x 1" (0.60 mm x 25 mm)
✓ FP6078	10ml Luer Lock with Hypodermic Needle 21G x 1¼" (0.80 mm x 32 mm)
✓ FP6013	10ml Luer Lock with Hypodermic Needle 21G x 1¼" (0.80 mm x 32 mm)
✓ FP6243	10ml Luer Lock with Hypodermic Needle 21G x 1¼" (0.80 mm x 32 mm)
✓ FP6014	20ml Luer Slip with Hypodermic Needle 21G x 1¼" (0.80 mm x 32 mm)
✓ FP6016	50ml Luer Slip with Hypodermic Needle 21G x 1¼" (0.80 mm x 32 mm)

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Sterile, single use, IV cannula

- ✓ FP6039 18G (Ø1.30mm x 45mm) with Injection Port Luer Lock, Flow Rate: 80 ml/min
- ✓ FP6040 20G (Ø1.10mm x 32mm) with Injection Port Luer Lock, Flow Rate: 54 ml/min
- ✓ FP6041 22G (Ø0.90mm x 25mm) with Injection Port Luer Lock, Flow Rate: 33 ml/min
- ✓ FP6042 24G (Ø0.70mm x 19mm) with Injection Port Luer Lock, Flow Rate: 20 ml/min
- ✓ FP6197 24G Neonates (Ø0.70mm x 19mm) with Small Wings without Injection Port, Flow Rate: 20 ml/min
- ✓ FP6218 26G Neonates (Ø0.60mm x 19mm) with Small Wings without Injection Port, Flow Rate: 13 ml/min
- ✓ FP6249 18G (Ø1.30mm x 32mm) with Injection Port Luer Lock, Flow Rate: 80 ml/min
- ✓ FP6250 18G (Ø1.30mm x 32mm) with Extra Injection Plug, With Injection Port Luer Lock, Flow Rate: 80 ml/min
- ✓ FP6251 18G (Ø1.30mm x 45mm) with Extra Injection Plug, with Injection Port Luer Lock, Flow Rate: 80 ml/min
- ✓ FP6252 20G (Ø1.10mm x 32mm) with Extra Injection Plug, with Injection Port Luer Lock, Flow Rate: 54 ml/min
- ✓ FP6253 22G (Ø0.90mm x 25mm) with Extra Injection Plug, with Injection Port Luer Lock, Flow Rate: 33 ml/min
- ✓ FP6254 24G (Ø0.70mm x 19mm) with Extra Injection Plug, with Injection Port Luer Lock, Flow Rate: 20 ml/min

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