3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-090

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa,

Sterile Hypodermic Syringe for Single Use
(for detailed list refer to Annex)

manufactured by company

Al Fateh Factory for Medical Supplies

Part(11) – Chemical industries block – Industrial Area West of Tahta, Sohag, Egypt

is manufactured under conditions fulfilling the quality system requirements of Annex V, of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The production quality assurance has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310415 and the Final protocol No. 310415/2019.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 9th, 2019