



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

EC CERTIFICATE

No. 2019-MDD/QS-051/A

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class IIa,

Sterile Hypodermic Syringe for Single Use
Trade name: Arrow Syringe
(for detailed list refer to Annex)

manufactured by company

Arrow for Medical Necessities

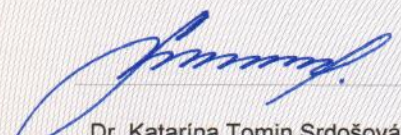
Parts no. (part of 59, 60, 62, 63) Industrial Zone Arab El Awamer, Abanob, Assuit, Egypt

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

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. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310386 and the Final protocols No. 310386/2019 and 310386A/2021.

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.



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

At Bratislava, on May 24th, 2021
Version A) supersedes the EC Certificate No. 2019-MDD/QS-051 issued on August 19th, 2020

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
00	September 9 th , 2019	310386	First issue of the Certificate
01	August 19 th , 2020	310386	Correction of typo mistake in Certificate - Annex V.
A	May 24 th , 2021	310386A	Add new models