



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

EC CERTIFICATE

No. 2016-MDD/QS-003/C

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
Type: Hypodermic Syringe, Safety Syringe and Insulin Syringe
(for detailed list refer to Annex, pages 1 to 3)

manufactured by company

International Company for Medical Necessities (I.CO)
3rd Industrial Zone Block No. 19&67, Abu-Tig, Assiut, 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. 310225 C; and the Final protocols No. 310225-A/2016, No. 310225-B/2018 and No. 310225 C/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 March 15th, 2021 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

In Bratislava, on February 27th, 2019
Version C) supersedes the EC Certificate No. 2016-MDD/QS-003/B issued on March 15th, 2018



ANNEX TO EC CERTIFICATE No. 2016-MDD/QS-003/C

issued for the company

International Company for Medical Necessities (I.CO)

3rd Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt

List of medical devices covered by the EC Certificate:

Product Name	Needle Size	Code	GMDN Code	Product Name	Needle Size	Code	GMDN Code
Hypodermic Syringe 3ml (3 parts)	23G x 1/4	A	13929	Hypodermic Syringe 5ml with Safety Needle	22G x 1/4	D1	13929
Hypodermic Syringe 3ml (3 parts)	24G x 1	B	13929	Hypodermic Syringe 10ml with Safety Needle	21G x 1/2	E1	13929
Hypodermic Syringe 3ml (3 parts)	25G x 5/8	C	13929	Hypodermic Syringe 20ml with Safety Needle	19G x 1/2	F1	13929
Hypodermic Syringe 5ml (3 parts)	22G x 1/4	D	13929	Hypodermic Syringe 50ml with Safety Needle	18G x 1/2	G1	13929
Hypodermic Syringe 10ml (3 parts)	21G x 1/2	E	13929	Hypodermic Syringe 1ml Insulin with Safety Needle	28G x 1/2	H1	35389
Hypodermic Syringe 20ml (3 parts)	19G x 1/2	F	13929	Safety Syringe 1ml Auto Disable	28G x 1/2	J1	35389
Hypodermic Syringe 50ml (3 parts)	18G x 1/2	G	13929	Safety Syringe 3ml Auto Disable	23G x 1/4	K1	13929
Hypodermic Syringe 1ml Insulin (3 parts)	28G x 1/2	H	35389	Safety Syringe 3ml Auto Disable	24G x 1	L1	13929
Hypodermic Syringe 1ml Insulin (Uni-body)	30G x 8mm	I	35389	Safety Syringe 3ml Auto Disable	25G x 5/8	M1	13929
Safety Syringe 1ml	28G x 1/2	J	13929	Safety Syringe 5ml Auto Disable	22G x 1/4	O1	13929
Safety Syringe 3ml	23G x 1/4	K	13929	Safety Syringe 10ml Auto Disable	21G x 1/2	P1	13929
Safety Syringe 3ml	24G x 1	L	13929	Safety Syringe 20ml Auto Disable	19G x 1/2	Q	13929
Safety Syringe 3ml	25G x 5/8	M	13929	Safety Syringe 50ml Auto Disable	18G x 1/2	R	13929
Safety Syringe 5ml	22G x 1/4	O	13929	Safety Syringe 1/2 ml Auto Disable (Uni-Body)	23G x 1	S	13929
Safety Syringe 10ml	21G x 1/2	P	13929	Safety Syringe 1/2 ml Auto Disable (Uni-Body)	25G x 5/8	S1	13929
Hypodermic Syringe 3ml with Safety Needle	23G x 1/4	A1	13929	Safety Syringe 1/2 ml Auto Disable	23G x 1	T	13929

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Hypodermic Syringe 3ml with Safety Needle	24G x 1	B1	13929	Hypodermic Syringe 20ml with Safety Needle Luer Lock	19G x 1 1/2	F1S	13929
Hypodermic Syringe 3ml with Safety Needle	25G x 5/8	C1	13929	Hypodermic Syringe 50ml with Safety Needle Luer Lock	18G x 1 1/2	G1S	13929
Hypodermic Syringe 3ml (3 parts) Luer Lock	23G x 1 1/4	AS	13929	Safety Syringes 3ml Auto Disable Luer Lock	23G x 1 1/4	K1S	13929
Hypodermic Syringe 3ml (3 parts) Luer Lock	24G x 1	BS	13929	Safety Syringes 3ml Auto Disable Luer Lock	24G x 1	L1S	13929
Hypodermic Syringe 3ml (3 parts) Luer Lock	25G x 5/8	CS	13929	Safety Syringes 3ml Auto Disable Luer Lock	25G x 5/8	M1S	13929
Hypodermic Syringe 5ml (3 parts) Luer Lock	22G x 1 1/4	DS	13929	Safety Syringes 5ml Auto Disable Luer Lock	22G x 1 1/4	O1S	13929
Hypodermic Syringe 10ml (3 parts) Luer Lock	21G x 1 1/2	ES	13929	Safety Syringes 10ml Auto Disable Luer Lock	21G x 1 1/2	P1S	13929
Hypodermic Syringe 20ml (3 parts) Luer Lock	19G x 1 1/2	FS	13929	Safety Syringes 20ml Auto Disable Luer Lock	19G x 1 1/2	QS	13929
Hypodermic Syringe 50ml (3 parts) Luer Lock	18G x 1 1/2	GS	13929	Safety Syringes 50ml Auto Disable Luer Lock	18G x 1 1/2	RS	13929
Hypodermic Syringe 3ml with Safety Needle Luer Lock	23G x 1 1/4	A1S	13929	Hypodermic Syringe 3ml (3 parts)	19G x 5/8	AV	13929
Hypodermic Syringe 3ml with Safety Needle Luer Lock	24G x 1	B1S	13929	Hypodermic Syringe 5ml (3 parts)	18G x 3/4	DV	13929
Hypodermic Syringe 3ml with Safety Needle Luer Lock	25G x 5/8	C1S	13929	Hypodermic Syringe 5ml (3 parts)	19G x 5/8	DV1	13929
Hypodermic Syringe 5ml with Safety Needle Luer Lock	22G x 1 1/4	D1S	13929	Hypodermic Syringe 5ml (3 parts)	18G x 1	DV2	13929
Safety Syringe 1/2 ml Auto Disable	25G x 5/8	T1	13929	Hypodermic Syringe 10ml (3 parts)	17G x 1	EV	13929
Safety Syringe 1/2 ml Auto Disable	27G x 1/2	T2	13929	Hypodermic Syringe 10ml (3 parts)	17G x 1 1/2	EV1	13929
Hypodermic Syringe 10ml with Safety Needle Luer Lock	21G x 1 1/2	E1S	13929	Hypodermic Syringe 20ml (3 parts)	16G x 1	FV	13929

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Hypodermic (3 parts)	Syringe	20ml	16G x 1 1/2	FV1	13929	Hypodermic (3 parts)	Syringe	50ml	21G x 1 1/2	GT	13929
Hypodermic (3 parts)	Syringe	20ml	18G x 1	FV2	13929	Hypodermic (3 parts)	Syringe	2ml	21G x 1 1/2	XT	13929
Hypodermic (3 parts)	Syringe	3ml	21G x 1 1/2	AT	13929	Hypodermic (3 parts)	Syringe	2ml	23G x 1 1/4	XT1	13929
Hypodermic (3 parts)	Syringe	5ml	21G x 1 1/2	DT	13929	Hypodermic (3 parts)	Syringe	2ml	21G x 5/8	XT2	13929
Hypodermic (3 parts)	Syringe	10ml	21G x 1 1/2	ET	13929	Hypodermic (3 parts)	Syringe	2ml	27G x 40mm	XT3	13929
Hypodermic (3 parts)	Syringe	20ml	21G x 1 1/2	FT	13929						

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