



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

## EC CERTIFICATE

No. 2020-MDD/QS-107/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**  
**Type: Hypodermic Syringe, Safety Syringe and Insulin Syringe**  
(for detailed list refer to Annex)

manufactured by company

**International Company for Medical Necessities (I.CO)**  
Site 1: 3<sup>rd</sup> Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt  
Site 2: Public Free Zone – Ismailia, 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. ICT\_61 and the Final protocol No. 310483/2020.

*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 26<sup>th</sup> 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 September 24<sup>th</sup>, 2020  
Certificate No. 2020-MDD/QS-107/A supersedes the EC Certificate No. 2020-MDD/QS-107 issued on August 12<sup>th</sup>, 2020 and the EC Certificate No. 2016-MDD/QS-003/A issued on May 16<sup>th</sup>, 2016.



Certificate history:

<b>Revision</b>	<b>Date of issue</b>	<b>Application for Conformity Assessment of MD number</b>	<b>Description</b>
<b>0</b>	<b>12/08/2020</b>	<b>310438</b>	<b>First Issue Certificate no. 2020-MDD/QS-107</b>
<b>A</b>	<b>24/09/2020</b>	<b>310438</b>	<b>Added missing information about superseding of certificate no. 2016-MDD/QS-003/A</b>





## ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-107/A

issued for the company

**International Company for Medical Necessities (I.CO)**

Site 1: 3<sup>rd</sup> Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt

Site 2: Public Free Zone – Ismailia, Egypt

### List of medical devices covered by the EC Certificate:

#	Product Name	Needle Size	Code	GMDN Code
1.	Hypodermic Syringe 3 ml (3 parts) Luer Slip	23 G x 1.1/4	A	63095
2.	Hypodermic Syringe 3 ml (3 parts) Luer Slip	24 G x 1	B	63095
3.	Hypodermic Syringe 3 ml (3 parts) Luer Slip	25 G x 5/8	C	63095
4.	Hypodermic Syringe 5 ml (3 parts) Luer Slip	22 G x 1.1/4	D	63095
5.	Hypodermic Syringe 10 ml (3 parts) Luer Slip	21 G x 1.1/2	E	63095
6.	Hypodermic Syringe 20 ml (3 parts) Luer Slip	19 G x 1.1/2	F	63095
7.	Hypodermic Syringe 50 ml (3 parts) Luer Slip	18 G x 1.1/2	G	63095
8.	Hypodermic Syringe 1 ml Insulin (3 parts) Luer Slip	28 G x 1/2	H	38501
9.	Hypodermic Syringe 1 ml Insulin (Uni-Body)	30 G x 8 mm	I	38501
10.	Safety Syringe 1 ml	28 G x 1/2	J	63095
11.	Safety Syringe 3 ml	23 G x 1.1/4	K	63095
12.	Safety Syringe 3 ml	24 G x 1	L	63095
13.	Safety Syringe 3 ml	25 G x 5/8	M	63095
14.	Safety Syringe 5 ml	22 G x 1.1/4	O	63095
15.	Safety Syringe 10 ml	21 G x 1.1/2	P	63095
16.	Hypodermic Syringe 3 ml with Safety Needle Luer Slip	23 G x 1.1/4	A1	63095
17.	Hypodermic Syringe 3 ml with Safety Needle Luer Slip	24 G x 1	B1	63095
18.	Hypodermic Syringe 3 ml with Safety Needle Luer Slip	25 G x 5/8	C1	63095
19.	Hypodermic Syringe 5 ml with Safety Needle Luer Slip	22 G x 1.1/4	D1	63095
20.	Hypodermic Syringe 10 ml with Safety Needle Luer Slip	21 G x 1.1/2	E1	63095
21.	Hypodermic Syringe 20 ml with Safety Needle Luer Slip	19 G x 1.1/2	F1	63095
22.	Hypodermic Syringe 50 ml with Safety Needle Luer Slip	18 G x 1.1/2	G1	63095
23.	Hypodermic Syringe 1 ml Insulin with Safety Needle	28 G x 1/2	H1	34973
24.	Safety Syringe 1 ml Auto Disable Luer Slip	28 G x 1/2	J1	38501
25.	Safety Syringe 3 ml Auto Disable Luer Slip	23 G x 1.1/4	K1	63095
26.	Safety Syringe 3 ml Auto Disable Luer Slip	24 G x 1	L1	63095

Page 1 of 4



At Bratislava, on September 24<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 2024

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





## ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-107/A

issued for the company

### International Company for Medical Necessities (I.CO)

Site 1: 3<sup>rd</sup> Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt

Site 2: Public Free Zone – Ismailia, Egypt

#### List of medical devices covered by the EC Certificate:

27.	Safety Syringe 3 ml Auto Disable Luer Slip	25 G x 5/8	M1	63095
28.	Safety Syringe 5 ml Auto Disable Luer Slip	22 G x 1.1/4	O1	63095
29.	Safety Syringe 10 ml Auto Disable Luer Slip	21 G x 1.1/2	P1	63095
30.	Safety Syringe 20 ml Auto Disable Luer Slip	19 G x 1.1/2	Q	63095
31.	Safety Syringe 50 ml Auto Disable Luer Slip	18 G x 1.1/2	R	63095
32.	Safety Syringe 1/2 ml Auto Disable (Uni-Body)	23 G x 1	S	63095
33.	Safety Syringe 1/2 ml Auto Disable (Uni-Body)	25 G x 5/8	S1	63095
34.	Safety Syringe 1/2 ml Auto Disable Luer Slip	23 G x 1	T	63095
35.	Safety Syringe 1/2 ml Auto Disable Luer Slip	25 G x 5/8	T1	63095
36.	Safety Syringe 1/2 ml Auto Disable Luer Slip	27 G x 1/2	T2	63095
37.	Hypodermic Syringe 3 ml (3 parts) Luer Lock	23 G x 1.1/4	AS	63095
38.	Hypodermic Syringe 3 ml (3 parts) Luer Lock	24 G x 1	BS	63095
39.	Hypodermic Syringe 3 ml (3 parts) Luer Lock	25 G x 5/8	CS	63095
40.	Hypodermic Syringe 5 ml (3 parts) Luer Lock	22 G x 1.1/4	DS	63095
41.	Hypodermic Syringe 10 ml (3 parts) Luer Lock	21 G x 1.1/2	ES	63095
42.	Hypodermic Syringe 20 ml (3 parts) Luer Lock	19 G x 1.1/2	FS	63095
43.	Hypodermic Syringe 50 ml (3 parts) Luer Lock	18 G x 1.1/2	GS	63095
44.	Hypodermic Syringe 3 ml with Safety Needle Luer Lock	23 G x 1.1/4	A1S	63095
45.	Hypodermic Syringe 3 ml with Safety Needle Luer Lock	24 G x 1	B1S	63095
46.	Hypodermic Syringe 3 ml with Safety Needle Luer Lock	25 G x 5/8	C1S	63095
47.	Hypodermic Syringe 5 ml with Safety Needle Luer Lock	22 G x 1.1/4	D1S	63095
48.	Hypodermic Syringe 10 ml with Safety Needle Luer Lock	21 G x 1.1/2	E1S	63095

Page 2 of 4



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

At Bratislava, on September 24<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 2024





## ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-107/A

issued for the company

### International Company for Medical Necessities (I.CO)

Site 1: 3<sup>rd</sup> Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt

Site 2: Public Free Zone – Ismailia, Egypt

#### List of medical devices covered by the EC Certificate:

49.	Hypodermic Syringe 20 ml with Safety Needle Luer Lock	19 G x 1.1/2	F1S	63095
50.	Hypodermic Syringe 50 ml with Safety Needle Luer Lock	18 G x 1.1/2	G1S	63095
51.	Safety Syringe 3 ml Auto Disable Luer Lock	23 G x 1.1/4	K1S	63095
52.	Safety Syringe 3 ml Auto Disable Luer Lock	24 G x 1	L1S	63095
53.	Safety Syringe 3 ml Auto Disable Luer Lock	25 G x 5/8	M1S	63095
54.	Safety Syringe 5 ml Auto Disable Luer Lock	22 G x 1.1/4	O1S	63095
55.	Safety Syringe 10 ml Auto Disable Luer Lock	21 G x 1.1/2	P1S	63095
56.	Safety Syringe 20 ml Auto Disable Luer Lock	19 G x 1.1/2	QS	63095
57.	Safety Syringe 50 ml Auto Disable Luer Lock	18 G x 1.1/2	RS	63095
58.	Hypodermic Syringe 3 ml (3 parts)	19 G x 5/8	AV	63095
59.	Hypodermic Syringe 5 ml (3 parts)	18 G x 3/4	DV	63095
60.	Hypodermic Syringe 5 ml (3 parts)	19 G x 5/8	DV1	63095
61.	Hypodermic Syringe 5 ml (3 parts)	18 G x 1	DV2	63095
62.	Hypodermic Syringe 10 ml (3 parts)	17 G x 1	EV	63095
63.	Hypodermic Syringe 10 ml (3 parts)	17 G x 1.1/2	EV1	63095
64.	Hypodermic Syringe 20 ml (3 parts)	16 G x 1	FV	63095
65.	Hypodermic Syringe 20 ml (3 parts)	16 G x 1.1/2	FV1	63095
66.	Hypodermic Syringe 20 ml (3 parts)	18 G x 1	FV2	63095
67.	Hypodermic Syringe 3 ml (3 parts)	21 G x 1.1/2	AT	63095
68.	Hypodermic Syringe 5 ml (3 parts)	21 G x 1.1/2	DT	63095
69.	Hypodermic Syringe 10 ml (3 parts)	21 G x 1.1/2	ET	63095
70.	Hypodermic Syringe 20 ml (3 parts)	21 G x 1.1/2	FT	63095
71.	Hypodermic Syringe 50 ml (3 parts)	21 G x 1.1/2	GT	63095
72.	Hypodermic Syringe 2 ml (3 parts)	21 G x 1.1/2	XT	63095
73.	Hypodermic Syringe 2 ml (3 parts)	23 G x 1.1/4	XT1	63095
74.	Hypodermic Syringe 2 ml (3 parts)	21 G x 5/8	XT2	63095

Page 3 of 4



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

At Bratislava, on September 24<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 2024





## ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-107/A

issued for the company

**International Company for Medical Necessities (I.CO)**

Site 1: 3<sup>rd</sup> Industrial Zone Block No. 19&67, Abu-Tig, Assiut, Egypt


Site 2: Public Free Zone – Ismailia, Egypt

### List of medical devices covered by the EC Certificate:

75.	Hypodermic Syringe 2 ml (3 parts)	27GX40mm	XT3	63095
76.	Hypodermic Syringe 2 ml (3 parts)	27GX50mm	XT4	63095
77.	Hypodermic Syringe 3 ml (3 parts)	23 G x 1	AX	63095
78.	Hypodermic Syringe 5 ml (3 parts)	23 G x 1	DX	63095
79.	Hypodermic Syringe 0.1 ml Auto Disable	26 G x $\frac{3}{8}$	FX	63095
80.	Hypodermic Syringe 0.1 ml Auto Disable	27 G x $\frac{3}{8}$	FX01	63095
81.	Hypodermic Syringe 0.05 ml Auto Disable	26 G x $\frac{3}{8}$	FX02	63095
82.	Hypodermic Syringe 0.05 ml Auto Disable	27 G x $\frac{3}{8}$	FX03	63095
83.	Hypodermic Syringe 2 ml Auto Disable	23 G x 1.1/4	XT5	63095

Page 4 of 4



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

At Bratislava, on September 24<sup>th</sup>, 2020  
Valid until May 26<sup>th</sup>, 2024