3EC® international

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

International Company For Medical Necessities (I.CO)

Site 01: 3rd Industrial Zone Block No. 17 &18 &19 & 20 & 67, Abu-Tig, Assiut, Egypt

Site 02: Public Free Zone - Ismalia, Egypt

has been assessed by 3EC International
and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

MANUFACTURING AND STERILIZATION OF NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES: STERILE SINGLE USE HYPODERMIC SYRINGES, STERILE SINGLE USE HYPODERMIC SYRINGES WITH RUP FEATURE, STERILE SINGLE USE AUTO DISABLE SYRINGES, STERILE INSULIN SYRIGNES, STERILE VENTED AND NON VENTED IV INFUSION SET, ORAL SYRINGES, INSULIN SYRINGES, CATHETER TIP FEEDING SYRINGES, TRUE FIT SYRINGES, IN VITRO DIAGNOSTIC MEDICAL DEVICE:BLOOD COLLECTION TUBE PACKAGING AND STERILIZATION OF (BLOOD COLLECTION NEEDLE, SPINAL ANESTHESIA NEEDLES, HYPODERMIC NEEDLES, PEN NEEDLES, DENTAL NEEDLES)

Certificate No.: M-0283/25 **Date of issuance: January 15th, 2025** **Original date of approval: May 17th, 2010**

This certificate is valid from **February 28th, 2025** to **February 27th, 2028** on condition that organization will maintain effective quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a. s.

Certification body 3EC International a. s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.

Digitally signed by Iurcu Nicolae
Date: 2026.07.31 09:33:06 EEST
Reason: MoldSign Signature
Location: Moldova
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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: 3rd 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 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. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on September 24th, 2020
Certificate No. 2020-MDD/QS-107/A supersedes the EC Certificate No. 2020-MDD/QS-107 issued on August 12th, 2020 and the EC Certificate No. 2016-MDD/QS-003/A issued on May 16th, 2016.

Certificate history:

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

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

issued for the company

International Company for Medical Necessities (I.CO)

Site 1: 3rd 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 x5/8	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

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

At Bratislava, on September 24th, 2020
Valid until May 26th, 2024

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

issued for the company

International Company for Medical Necessities (I.CO)

Site 1: 3rd 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 ½ ml Auto Disable (Uni-Body)	23 G x 1	S	63095
33.	Safety Syringe ½ ml Auto Disable (Uni-Body)	25 G x 5/8	S1	63095
34.	Safety Syringe ½ ml Auto Disable Luer Slip	23 G x 1	T	63095
35.	Safety Syringe ½ ml Auto Disable Luer Slip	25 G x 5/8	T1	63095
36.	Safety Syringe ½ 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

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

At Bratislava, on September 24th, 2020
Valid until May 26th, 2024

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

issued for the company

International Company for Medical Necessities (I.CO)

Site 1: 3rd 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

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

At Bratislava, on September 24th, 2020
Valid until May 26th, 2024

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

issued for the company

International Company for Medical Necessities (I.CO)

Site 1: 3rd 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 × 3/8	FX	63095
80.	Hypodermic Syringe 0.1 ml Auto Disable	27 G × 3/8	FX01	63095
81.	Hypodermic Syringe 0.05 ml Auto Disable	26 G × 3/8	FX02	63095
82.	Hypodermic Syringe 0.05 ml Auto Disable	27 G × 3/8	FX03	63095
83.	Hypodermic Syringe 2 ml Auto Disable	23 G x 1.1/4	XT5	63095

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

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

At Bratislava, on September 24th, 2020
Valid until May 26th, 2024

International Company for Medical Necessities
Site1:3rd Industrial Zone Block No. 19&67 Abou-Teeg, El-Zaraby, Assuit, Egypt
Site2: Public Free Zone – Ismailia, Egypt

Attn. Ahmed Adel Khalil / general manager

Our reference	***Contact person***	BRATISLAVA
MIT/2024/P107	Michal Tomin / +421 915 366 774	13.5.2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

International Company for Medical Necessities
Site1:3rd Industrial Zone Block No. 19&67 Abou-Teeg, El-Zaraby, Assuit, Egypt
Site2: Public Free Zone – Ismailia, Egypt

SRN Number (if available): EG-MF-000032919

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

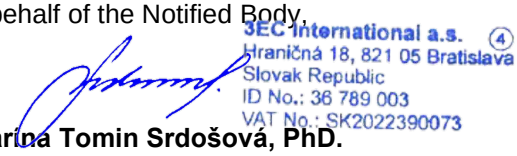
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Hypodermic Syringe for Single use **Trade name: Hypodermic Syringe, Safety Syringe and Insulin Syringe** **Models:** Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 23 G x 1.1/4, Code-A; Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 24 G x 1, Code-B; Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 25 G x 5/8, Code-C; Hypodermic Syringe 5 ml (3 parts) Luer Slip: Needle size: 22 G x 1.1/4, Code-D; Hypodermic Syringe 10 ml (3 parts) Luer Slip: Needle size: 21 G x 1.1/2, Code-E; Hypodermic Syringe 20 ml (3 parts) Luer Slip: Needle size: 19 G x 1.1/2, Code-F; Hypodermic Syringe 50 ml (3 parts) Luer Slip : Needle size: 18 G x 1.1/2, Code-G; Hypodermic Syringe 1 ml Insulin (3 parts) Luer Slip: Needle size: 28 G x ½, Code-H; Hypodermic Syringe 1 ml Insulin (Uni-Body): Needle size: 30 G x 8 mm, Code-I; Safety Syringe 1 ml: Needle size: 28 G x ½, Code-J; Safety Syringe 3 ml: Needle size: 23 G x 1.1/4, Code-K; Safety Syringe 3 ml: Needle size: 24 G x 1, Code-L; Safety Syringe 3 ml: Needle size: 25 G x5/8, Code-M; Safety Syringe 5 ml: Needle size: 22 G x 1.1/4, Code-O; Safety Syringe 10 ml: Needle size: 21 G x 1.1/2, Code-P; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 23 G x 1.1/4, Code-A1; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 24 G x 1, Code-B1; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 25 G x 5/8, Code-C1;	Class IIa	N/A	2020-MDD/QS-107/A NB2265

Hypodermic Syringe 5 ml with Safety Needle Luer Slip: Needle size: 22 G x 1.1/4, Code-D1; Hypodermic Syringe 10 ml with Safety Needle Luer Slip: Needle size: 21 G x 1.1/2, Code-E1; Hypodermic Syringe 20 ml with Safety Needle Luer Slip: Needle size: 19 G x 1.1/2, Code-F1 Hypodermic Syringe 50 ml with Safety Needle Luer Slip: Needle size: 18 G x 1.1/2, Code-G1; Hypodermic Syringe 1 ml Insulin with Safety Needle : Needle size: 28 G x 1/2, Code-H1; Safety Syringe 1 ml Auto Disable Luer Slip: Needle size: 28 G x 1/2, Code-J1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 3 G x 1.1/4, Code-K1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 24 G x 1, Code-L1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 25 G x 5/8, Code-M1; Safety Syringe 5 ml Auto Disable Luer Slip: Needle size: 22 G x 1.1/4, Code-O1; Safety Syringe 10 ml Auto Disable Luer Slip: Needle size: 21 G x 1.1/2, Code-P1; Safety Syringe 20 ml Auto Disable Luer Slip: Needle size: 19 G x 1.1/2, Code-Q; Safety Syringe 50 ml Auto Disable Luer Slip: Needle size: 18 G x 1.1/2, Code-R; Safety Syringe ½ ml Auto Disable (Uni-Body)**:** Needle size: 23 G x 1, Code-S; Safety Syringe ½ ml Auto Disable (Uni-Body)**:** Needle size: 25 G x 5/8, Code-S1; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 23 G x 1, Code-T; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 25 G x 5/8, Code-T1; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 27 G x 1/2, Code-T2; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 23 G x 1.1/4, Code-AS; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 24 G x 1, Code-BS; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 25 G x 5/8, Code-CS; Hypodermic Syringe 5 ml (3 parts) Luer Lock: Needle size: 22 G x 1.1/4, Code-DS; Hypodermic Syringe 10 ml (3 parts) Luer Lock: Needle size: 21 G x 1.1/2, Code-ES; Hypodermic Syringe 20 ml (3 parts) Luer Lock: Needle size: 19 G x 1.1/2, Code-FS; Hypodermic Syringe 50 ml (3 parts) Luer Lock: Needle size: 18 G x 1.1/2, Code-GS; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 23 G x 1.1/4, Code-A1S; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 24 G x 1, Code-B1S; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 25 G x 5/8, Code-C1S;			

Hypodermic Syringe 5 ml with Safety Needle Luer Lock: Needle size: 22 G x 1.1/4, Code-D1S; Hypodermic Syringe 10 ml with Safety Needle Luer Lock: Needle size: 21 G x 1.1/2, Code-E1S; Hypodermic Syringe 20 ml with Safety Needle Luer Lock: Needle size: 19 G x 1.1/2, Code-F1S; Hypodermic Syringe 50 ml with Safety Needle Luer Lock: Needle size: 18 G x 1.1/2, Code-G1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 23 G x 1.1/4, Code-K1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 24 G x 1, Code-L1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 25 G x 5/8, Code-M1S; Safety Syringe 5 ml Auto Disable Luer Lock: Needle size: 22 G x 1.1/4, Code-O1S; Safety Syringe 10 ml Auto Disable Luer Lock: Needle size: 21 G x 1.1/2, Code-P1S; Safety Syringe 20 ml Auto Disable Luer Lock: Needle size: 19 G x 1.1/2, Code-QS; Safety Syringe 50 ml Auto Disable Luer Lock: Needle size: 18 G x 1.1/2, Code-RS; Hypodermic Syringe 3 ml (3 parts): Needle size: 19 G x 5/8, Code-AV; Hypodermic Syringe 5 ml (3 parts): Needle size: 18 G x 3/4, Code-DV; C 19 G x 5/8, Code-DV1; Hypodermic Syringe 5 ml (3 parts): Needle size: 18 G x 1, Code-DV2; Hypodermic Syringe 10 ml (3 parts): Needle size: 17 G x 1, Code-EV; Hypodermic Syringe 10 ml (3 parts): Needle size: 17 G x 1.1/2, Code-EV1; Hypodermic Syringe 20 ml (3 parts): Needle size: 16 G x 1, Code-FV; Hypodermic Syringe 20 ml (3 parts): Needle size: 16 G x 1.1/2, Code-FV1; Hypodermic Syringe 20 ml (3 parts): Needle size: 18 G x 1, Code-FV2; Hypodermic Syringe 3 ml (3 parts): Needle size: 21 G x 1.1/2, Code-AT; Hypodermic Syringe 5 ml (3 parts): Needle size: 21 G x 1.1/2, Code-DT; Hypodermic Syringe 10 ml (3 parts): Needle size: 21 G x 1.1/2, Code-ET; Hypodermic Syringe 20 ml (3 parts): Needle size: 21 G x 1.1/2, Code-FT; Hypodermic Syringe 50 ml (3 parts): Needle size: 21 G x 1.1/2, Code-GT; Hypodermic Syringe 2 ml (3 parts): Needle size: 21 G x 1.1/2, Code-XT; Hypodermic Syringe 2 ml (3 parts): Needle size: 23 G x 1.1/4, Code-XT1; Hypodermic Syringe 2 ml (3 parts): Needle size: 21 G x 5/8, Code-XT2; Hypodermic Syringe 2 ml (3 parts): Needle size: 27GX40mm, Code-XT3; Hypodermic Syringe 2 ml (3 parts): Needle size: 27GX50mm, Code-XT4;			

Hypodermic Syringe 3 ml (3 parts): Needle size: 23 G x 1, Code-AX; Hypodermic Syringe 5 ml (3 parts): Needle size: 23 G x 1, Code-DX; Hypodermic Syringe 0.1 ml Auto Disable: Needle size: 26 G × ⅜, Code-FX; Hypodermic Syringe 0.1 ml Auto Disable: Needle size: 27 G × ⅜, Code-FX01; Hypodermic Syringe 0.5 ml Auto Disable: Needle size: 26 G × ⅜, Code-FX02; Hypodermic Syringe 0.5 ml Auto Disable: Needle size: 27 G × ⅜, Code-FX03; Hypodermic Syringe 2 ml Auto Disable: Needle size: 23 G x 1.1/4, Code-XT5			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/5/13	MIT/2024/P107	Initial issue

International Company for Medical Necessities
Site1: Industrial Zone Block No. 17&18&19&20&67, Assiut, Abou-Teeg, El-Zaraby, Egypt
Site2: Public Free Zone – Ismailia, Egypt

Attn. Ahmed Adel Khalil / general manager

Our reference	***Contact person***	BRATISLAVA
MIT/2024/P107.1	Michal Tomin / +421 915 366 774	9.1.2025

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a. s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

International Company for Medical Necessities
Site1: Industrial Zone Block No. 17&18&19&20&67, Assiut, Abou-Teeg, El-Zaraby, Egypt
Site2: Public Free Zone – Ismailia, Egypt

SRN Number (if available): EG-MF-000032919

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

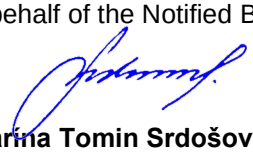
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Hypodermic Syringe for Single use **Trade name: Hypodermic Syringe, Safety Syringe and Insulin Syringe** **Models:** Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 23 G x 1.1/4, Code-A; Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 24 G x 1, Code-B; Hypodermic Syringe 3 ml (3 parts) Luer Slip: Needle size: 25 G x 5/8, Code-C; Hypodermic Syringe 5 ml (3 parts) Luer Slip: Needle size: 22 G x 1.1/4, Code-D; Hypodermic Syringe 10 ml (3 parts) Luer Slip: Needle size: 21 G x 1.1/2, Code-E; Hypodermic Syringe 20 ml (3 parts) Luer Slip: Needle size: 19 G x 1.1/2, Code-F; Hypodermic Syringe 50 ml (3 parts) Luer Slip : Needle size: 18 G x 1.1/2, Code-G; Hypodermic Syringe 1 ml Insulin (3 parts) Luer Slip: Needle size: 28 G x ½, Code-H; Hypodermic Syringe 1 ml Insulin (Uni-Body): Needle size: 30 G x 8 mm, Code-I; Safety Syringe 1 ml: Needle size: 28 G x ½, Code-J; Safety Syringe 3 ml: Needle size: 23 G x 1.1/4, Code-K; Safety Syringe 3 ml: Needle size: 24 G x 1, Code-L; Safety Syringe 3 ml: Needle size: 25 G x5/8, Code-M; Safety Syringe 5 ml: Needle size: 22 G x 1.1/4, Code-O; Safety Syringe 10 ml: Needle size: 21 G x 1.1/2, Code-P; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 23 G x 1.1/4, Code-A1; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 24 G x 1, Code-B1; Hypodermic Syringe 3 ml with Safety Needle Luer Slip: Needle size: 25 G x 5/8, Code-C1;	Class IIa	N/A	2020-MDD/QS-107/A NB2265

Hypodermic Syringe 5 ml with Safety Needle Luer Slip: Needle size: 22 G x 1.1/4, Code-D1; Hypodermic Syringe 10 ml with Safety Needle Luer Slip: Needle size: 21 G x 1.1/2, Code-E1; Hypodermic Syringe 20 ml with Safety Needle Luer Slip: Needle size: 19 G x 1.1/2, Code-F1 Hypodermic Syringe 50 ml with Safety Needle Luer Slip: Needle size: 18 G x 1.1/2, Code-G1; Hypodermic Syringe 1 ml Insulin with Safety Needle : Needle size: 28 G x 1/2, Code-H1; Safety Syringe 1 ml Auto Disable Luer Slip: Needle size: 28 G x 1/2, Code-J1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 23 G x 1.1/4, Code-K1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 24 G x 1, Code-L1; Safety Syringe 3 ml Auto Disable Luer Slip: Needle size: 25 G x 5/8, Code-M1; Safety Syringe 5 ml Auto Disable Luer Slip: Needle size: 22 G x 1.1/4, Code-O1; Safety Syringe 10 ml Auto Disable Luer Slip: Needle size: 21 G x 1.1/2, Code-P1; Safety Syringe 20 ml Auto Disable Luer Slip: Needle size: 19 G x 1.1/2, Code-Q; Safety Syringe 50 ml Auto Disable Luer Slip: Needle size: 18 G x 1.1/2, Code-R; Safety Syringe ½ ml Auto Disable (Uni-Body)**:** Needle size: 23 G x 1, Code-S; Safety Syringe ½ ml Auto Disable (Uni-Body)**:** Needle size: 25 G x 5/8, Code-S1; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 23 G x 1, Code-T; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 25 G x 5/8, Code-T1; Safety Syringe ½ ml Auto Disable Luer Slip: Needle size: 27 G x 1/2, Code-T2; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 23 G x 1.1/4, Code-AS; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 24 G x 1, Code-BS; Hypodermic Syringe 3 ml (3 parts) Luer Lock: Needle size: 25 G x 5/8, Code-CS; Hypodermic Syringe 5 ml (3 parts) Luer Lock: Needle size: 22 G x 1.1/4, Code-DS; Hypodermic Syringe 10 ml (3 parts) Luer Lock: Needle size: 21 G x 1.1/2, Code-ES; Hypodermic Syringe 20 ml (3 parts) Luer Lock: Needle size: 19 G x 1.1/2, Code-FS; Hypodermic Syringe 50 ml (3 parts) Luer Lock: Needle size: 18 G x 1.1/2, Code-GS; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 23 G x 1.1/4, Code-A1S; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 24 G x 1, Code-B1S; Hypodermic Syringe 3 ml with Safety Needle Luer Lock: Needle size: 25 G x 5/8, Code-C1S;			

Hypodermic Syringe 5 ml with Safety Needle Luer Lock: Needle size: 22 G x 1.1/4, Code-D1S; Hypodermic Syringe 10 ml with Safety Needle Luer Lock: Needle size: 21 G x 1.1/2, Code-E1S; Hypodermic Syringe 20 ml with Safety Needle Luer Lock: Needle size: 19 G x 1.1/2, Code-F1S; Hypodermic Syringe 50 ml with Safety Needle Luer Lock: Needle size: 18 G x 1.1/2, Code-G1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 23 G x 1.1/4, Code-K1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 24 G x 1, Code-L1S; Safety Syringe 3 ml Auto Disable Luer Lock: Needle size: 25 G x 5/8, Code-M1S; Safety Syringe 5 ml Auto Disable Luer Lock: Needle size: 22 G x 1.1/4, Code-O1S; Safety Syringe 10 ml Auto Disable Luer Lock: Needle size: 21 G x 1.1/2, Code-P1S; Safety Syringe 20 ml Auto Disable Luer Lock: Needle size: 19 G x 1.1/2, Code-QS; Safety Syringe 50 ml Auto Disable Luer Lock: Needle size: 18 G x 1.1/2, Code-RS; Hypodermic Syringe 3 ml (3 parts): Needle size: 19 G x 5/8, Code-AV; Hypodermic Syringe 5 ml (3 parts): Needle size: 18 G x 3/4, Code-DV; Hypodermic Syringe 5 ml (3 parts): Needle size: 19 G x 5/8, Code-DV1; Hypodermic Syringe 5 ml (3 parts): Needle size: 18 G x 1, Code-DV2; Hypodermic Syringe 10 ml (3 parts): Needle size: 17 G x 1, Code-EV; Hypodermic Syringe 10 ml (3 parts): Needle size: 17 G x 1.1/2, Code-EV1; Hypodermic Syringe 20 ml (3 parts): Needle size: 16 G x 1, Code-FV; Hypodermic Syringe 20 ml (3 parts): Needle size: 16 G x 1.1/2, Code-FV1; Hypodermic Syringe 20 ml (3 parts): Needle size: 18 G x 1, Code-FV2; Hypodermic Syringe 3 ml (3 parts): Needle size: 21 G x 1.1/2, Code-AT; Hypodermic Syringe 5 ml (3 parts): Needle size: 21 G x 1.1/2, Code-DT; Hypodermic Syringe 10 ml (3 parts): Needle size: 21 G x 1.1/2, Code-ET; Hypodermic Syringe 20 ml (3 parts): Needle size: 21 G x 1.1/2, Code-FT; Hypodermic Syringe 50 ml (3 parts): Needle size: 21 G x 1.1/2, Code-GT; Hypodermic Syringe 2 ml (3 parts): Needle size: 21 G x 1.1/2, Code-XT; Hypodermic Syringe 2 ml (3 parts): Needle size: 23 G x 1.1/4, Code-XT1; Hypodermic Syringe 2 ml (3 parts): Needle size: 21 G x 5/8, Code-XT2; Hypodermic Syringe 2 ml (3 parts): Needle size: 27GX40mm, Code-XT3; Hypodermic Syringe 2 ml (3 parts): Needle size: 27GX50mm, Code-XT4;			

Hypodermic Syringe 3 ml (3 parts): Needle size: 23 G x 1, Code-AX; Hypodermic Syringe 5 ml (3 parts): Needle size: 23 G x 1, Code-DX; Hypodermic Syringe 0.1 ml Auto Disable: Needle size: 26 G × ⅜, Code-FX; Hypodermic Syringe 0.1 ml Auto Disable: Needle size: 27 G × ⅜, Code-FX01; Hypodermic Syringe 0.5 ml Auto Disable: Needle size: 26 G × ⅜, Code-FX02; Hypodermic Syringe 0.5 ml Auto Disable: Needle size: 27 G × ⅜, Code-FX03; Hypodermic Syringe 2 ml Auto Disable: Needle size: 23 G x 1.1/4, Code-XT5			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/5/13	MIT/2024/P107	Initial issue
2025/1/9	MIT/2024/P107.1	After the appropriate surveillance audit – change of site 1 address on first page of extension confirmation letter – from old 3rd Industrial Zone Block No. 19&67 Abou-Teeg, El-Zaraby, Assuit, Egypt to new one site 1 Industrial Zone Block No. 17&18&19&20&67, Assiut, Abou-Teeg, El-Zaraby, Egypt.