

## EC Declaration of Conformity

MDD 93/42/EEC as amended (Annex V)

Manufacturer	
<b>Name</b>	: International Company For Medical Necessities.
<b>legal manufacturer Address</b>	: 3rd Industrial Zone Block No. 19,67 Abu-Tig, Assiut, Egypt.
<b>manufacturing Site 1</b>	: International Company For Medical Necessities 3rd Industrial Zone Block No. 19,67 Abu-Tig, Assiut, Egypt
<b>manufacturing Site 2</b>	: International Company For Medical Necessities Public Free Zone – Ismailia ,Egypt
<b>Tade Name</b>	: I.CO
<b>Product Name</b>	: Sterile Hypodermic Syringe for Single Use
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Notified Body	
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<b>Website</b>	: <a href="http://www.obelis.net">www.obelis.net</a>
Declares that the Products	
<b>Product Name</b>	: Sterile Hypodermic Syringe for Single Use
<b>Product Variants</b>	: Hypodermic Syringe, Safety Syringe and Insulin Syringe
<b>Description</b>	: Sterile For Single Use
<b>Class</b>	: IIa,Rule 6
<b>Codes</b>	: Annex A

**GMDN Codes**

**: 63095 General-purpose syringe/needle**

A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a non-retractable needle is included, either attached or detached (usually capped for user protection). It is intended for various medical applications and is not dedicated to medication administration. The syringe is typically made of plastic and silicone materials and may have anti-stick plunger allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

**38501 Insulin syringe/needle, basic**

A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used to administer an injection of insulin to a patient subcutaneously; a non-retractable needle is included, either attached or detached (usually capped for user protection). The syringe is typically made of plastic and silicone materials and will have plunger anti-sticking properties allowing smooth plunger movement. It can be used by healthcare personnel or patient, and will allow for the aspiration of the pharmaceutical from its container for direct administration to the patient or via an intravenous (IV) port, heparin lock, or saline lock. This is a single-use device

**Intended use:-**

Used for Aspiration of fluids or for injection of fluids immediately after filling .it is most commonly used for administrations of medications

**Annex A:Product Variants**

#	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	35501
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
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
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
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 3/8	FX	63095
80.	Hypodermic Syringe 0.1 ml Auto Disable	27 G x 3/8	FX01	63095
81.	Hypodermic Syringe 0.05 ml Auto Disable	26 G x 3/8	FX02	63095
82.	Hypodermic Syringe 0.05 ml Auto Disable	27 G x 3/8	FX03	63095
83.	Hypodermic Syringe 2 ml Auto Disable	23 G x 1.1/4	XT5	63095

- Applied harmonized Standards as the following table:

Document NO	Document Title
ISO7886-1 :2017	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 7886-3 :2005	Sterile hypodermic syringes for single use – Part 3: Auto disable syringes for fixed-dose immunization
ISO 7886-4 :2018	Sterile hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature
ISO 8537: 2016	Sterile single-use syringes, with or without needle, for insulin
ISO 7864: 2016	Sterile hypodermic needle for single use

ISO 80369-7 : 2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic application
ISO 13485 : 2016	Medical Devices QMS-Requirements for Regulatory Purposes
EN ISO 14971 : 2012	Medical devices-Application of risk management to medical devices
ISO 10005 :2018	Guidance for Quality Plans
ISO 10007: 2017	Quality Management Systems – Guidelines for Configuration Management
ISO 10013 :2001	Guidelines For Quality Management System Documentation
ISO 19011 : 2018	Guidelines for Quality and-or Env. Management System Auditing
EN ISO 11607-2 : 2019	Packaging for terminally sterilized medical devices Part2: Validation Requirements for forming, sealing and assembly processes.
ISO 10993-1: 2018	Biological evaluation of MDs Part1: Evaluation and testing
ISO 10993-5 : 2009	Biological evaluation of MDs Part5: Tests for in vitro cytotoxicity
ISO 10993-7: 2008	Biological evaluation of MDs Part 7: Ethylene oxide Sterilization residuals
ISO 10993-10:- 2010	Biological evaluation of MDs Part10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:-2017	Biological evaluation of MDs Part11: Tests for systemic toxicity
ISO 14644-1: 2019	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness
ISO 14644-3: 2019	Cleanrooms and associated controlled environments Part 3: Test methods
ISO 14644-5 : 2004	Cleanrooms and associated controlled environments Part 5: operations
ISO 14644-8 : 2013	Cleanrooms and associated controlled environments Part 8: evaluation and interpretation of bio contamination data
ISO 14698-1 : 2003	Cleanrooms and Associated Controlled Environments-Bio contaminations Control Part1: General Principles and Methods
ISO 14698-2 :2003	Cleanrooms and Associated Controlled Environments-Bio contaminations Control Part2: Evaluation and interpretation of Bio contamination Data
ISO 11135-1: 2007	Sterilization-Ethylene oxide-Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11737-1 :2018	Sterilization of MDs-Microbiological Methods Determination of a population of microorganisms on products
ISO 11737-3: 2004	Sterilization of MDs-Microbiological Methods Part3:Guidance on evaluation and interpretation of bioburden data
ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
ISO 11138-1 : 2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2 : 2017	Part 1: guidance on the selection of biological indicators for ethylene oxide sterilization

ISO 15223-1 :2016	Graphical Symbols for Use in the Labeling of MDs
EN ISO 11607-1: 2019	Packaging for terminally sterilized medical devices Part1: Requirements for materials, sterile barrier systems and packing systems.

- *International Company For Medical Necessities declares that the product Sterile Hypodermic Syringe for single use and its variants are in conformity with the essential requirement and provisions of the Council directive 93/42/EEC & are subject to the procedure set out in Annex V of directive 93/42/EEC as amended.*

**General Manager**

**Dr. Ahmed Adel Khalil**

Date :14-12-2020

