

DECLARATION OF CONFORMITY

Legal Manufacturer:	WELLEX Company Limited Cairo-Ismailia desert Road, Ismailia Public Free Zone, 41639 Ismailia City, Egypt
Manufacturing Site(s):	WELLEX Company Limited Cairo-Ismailia desert Road, Ismailia Public Free Zone, 41639 Ismailia City, Egypt
EU Authorized Representative:	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany
Product:	IV Cannula With Port UMDN Code: 12748 Indication of Use: Intended to access the peripheral veins of the patient's blood system for re-hydration, parenteral nutrition, medication delivery, blood transfusion and monitoring purposes. A listing of Codes is included in Attachment 1 of this document.
Classification:	Class IIa device in conformity with Annex IX, Rule 7 in the Medical Device Directive 93/42/EEC (amended by 2007/47/EC)
Standards Applied conforming of the product with the regulatory requirements	<ul style="list-style-type: none">• EN ISO 10555-1: 2013 + /A1:2017• EN ISO 10555-5: 2013• EN ISO 9626:2016• EN ISO 80369-1:2018• EN ISO 80369-7:2016• EN ISO 80369-20:2015• EN ISO 13485:2016 + /AC:2018• EN ISO 15223-1:2016• EN ISO 14644-1:2015• EN ISO 11135:2014• EN ISO 11607-1:2017• EN ISO 11607-2:2017• EN ISO 14971:2012

- EN ISO 10993-1:2009 + /AC:2010
- EN ISO 10993-5:2009
- EN ISO 10993-7:2008 + /AC:2009
- EN ISO 10993-10:2013

We, WELLEX Company Limited, declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices (amended by 2007/47/EC). This declaration is made under Annex V of this directive. All Supporting Information is retained under the control of WELLEX Company.

Notified Body
TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 MÜNCHEN, Germany

EC Notified Body Number
0123

EC Certificates	
Certificate Name	Certificate Number / Validity
Annex V, Certificate number	G2 101573 0006 Rev.00 / Valid until: 2024-04-13
EN ISO 13485:2016 Certificate Number	Q6 101573 0007 Rev.01 / Valid until: 2025-04-13

Date of First CE Marking: 09-08-2019

Signature, Date of Issue:
Name: Angie Ahmed

Title: Director, Quality

Signature: Angie Ahmed
Date: 01 Aug. 2022

Name: Ahmed Mohammady

Title: CEO of WELLEX Company

Signature: Ahmed Mohammady
Date: 01 Aug. 2022

Attachment 1

Device's Reference Numbers are listed below.

#	Code	Product Name / Size
1.	FIV143OR	IV Cannula with wings&Injection port (14G)
2.	FIV163GR	IV Cannula with wings&Injection port (16G)
3.	FIV183GR	IV Cannula with wings&Injection port (18G)
4.	FIV203PK	IV Cannula with wings&Injection port (20G)
5.	FIV223BU	IV Cannula with wings&Injection port (22G)
6.	FIV243YW	IV Cannula with wings&Injection port (24G)
7.	FIV263VO	IV Cannula with wings&Injection port (26G)
8.	FIVP14OR	PEN IV Cannula (14G)
9.	FIVP16GR	PEN IV Cannula (16G)
10.	FIVP18GR	PEN IV Cannula (18G)
11.	FIVP20PK	PEN IV Cannula (20G)
12.	FIVP22BU	PEN IV Cannula (22G)
13.	FIVP24YW	PEN IV Cannula (24G)
14.	FIVP26VO	PEN IV Cannula (26G)
15.	FIVS14OR	Safety IV Cannula (14G)
16.	FIVS16GR	Safety IV Cannula (16G)
17.	FIVS18GR	Safety IV Cannula (18G)
18.	FIVS20PK	Safety IV Cannula (20G)
19.	FIVS22BU	Safety IV Cannula (22G)
20.	FIVS24YW	Safety IV Cannula (24G)
21.	FIVS26VO	Safety IV Cannula (26G)