

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:	Anaesthesia Needle Set UMDN Code: 34842 Indication of Use: Intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an EP catheter. A listing of Codes is included in Attachment 1 of this document.
Classification:	Class IIa device in conformity with Annex V, 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 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 10993-4:2017• 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 Limited.

Notified Body

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

EC Notified Body Number

0123

Quality 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: 21-09-2020

Signature, Date of Issue:

Name: Angie Ahmed

Title: Director, Regulatory Affairs

Signature: Angie Ahmed **Date:** 2nd Aug. 2022



Name: Ahmed Mohammady

Title: CEO of WELLEX Company

Signature: Ahmed Mohammady **Date:** 2nd Aug. 2022

Attachment 1**Device's Reference Numbers are listed below.**

#	Code	Description
1.	FEP1935K	Anaesthesia Needle Set (Pediatric) (Set content: Anaesthesia Needle 19G*35mm (Huber Point), Catheter 22G*1000mm Single Hole type, EP Filter , L.O.R Syringe 10ml)
2.	FEP1950K	Anaesthesia Needle Set (Pediatric) (Set content: Anaesthesia Needle 19G*50mm (Huber Point), Catheter 22G*1000mm Single Hole type, EP Filter , L.O.R Syringe 10ml)
3.	FEP1890K	Anaesthesia Needle Set (Adult) (Set content: Anaesthesia Needle 18G*90mm (Huber Point), Catheter 20G*1000mm Closed tip with 3 lateral eyes, EP Filter , L.O.R Syringe 10ml)
4.	FEP1880K	Anaesthesia Needle Set (Adult) (Set content: Anaesthesia Needle 18G*80mm (Huber Point), Catheter 20G*1000mm Closed tip with 3 lateral eyes, EP Filter , L.O.R Syringe 10ml)
5.	FEP1790K	Anaesthesia Needle Set (Adult) (Set content: Anaesthesia Needle 17G*90mm (Huber Point), Catheter 20G*1000mm Closed tip with 3 lateral eyes, EP Filter , L.O.R Syringe 10ml)
6.	FEP1780K	Anaesthesia Needle Set (Adult) (Set content: Anaesthesia Needle 17G*80mm (Huber Point), Catheter 20G*1000mm Closed tip with 3 lateral eyes, EP Filter , L.O.R Syringe 10ml)