

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 Needles****UMDN Code: 12753**

Intended use: Intended for use in injecting local
anesthetics and/or analgesics into a patient to provide
regional anesthesia and/or analgesia and/or to
facilitate the placement of a catheter.

A listing of Codes is included in Attachment 1 of this
document.

Classification:

Class IIa device in conformity with Annex IX, Rule 6 in
the Medical Device Directive 93/42/EEC (amended by
2007/47/EC)

**Standards Applied conform
complying of the product with the
regulatory requirements**

- EN ISO 9626:2016
- EN ISO 7864: 2016
- EN ISO 80369-1:2018
- EN ISO 80369-7:2017
- 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

Digitally signed by Ostapciuc Alexandr
Date: 2023.08.22 14:54:35 EEST
Reason: MoldSign Signature
Location: Moldova

**WELLEX Company Limited****EC Declaration of Conformity "Anaesthesia Needles"****DOC No.: DOC-22/Rev.01, Dated: 1 Aug. 2022****Page 1 of 3**

- 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 the Legal Manufacturer.

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: 21-09-2020

Signature, Date of Issue:

Name: Angie Ahmed

Title: Director, Regulatory Affairs

Signature: Angie Ahmed **Date:** 01 Aug. 2022



Name: Ahmed Mohammady

Title: CEO of WELLEX Company

Signature: Ahmed Mohammady **Date:** 01 Aug. 2022

WELLEX Company Limited

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Attachment 1

Device's Reference Numbers are listed below.

#	Code	Product Name / Size
1.	FS1850Q0	Anaesthesia needle, Quincke bevel type, 18G*50mm
2.	FS1875Q0	Anaesthesia needle, Quincke bevel type, 18G*75mm
3.	FS1890Q0	Anaesthesia needle, Quincke bevel type, 18G*90mm
4.	FS1950Q0	Anaesthesia needle, Quincke bevel type, 19G*50mm
5.	FS1975Q0	Anaesthesia needle, Quincke bevel type, 19G*75mm
6.	FS1990Q0	Anaesthesia needle, Quincke bevel type, 19G*90mm
7.	FS2038Q0	Anaesthesia needle, Quincke bevel type, 20G*38mm
8.	FS2050Q0	Anaesthesia needle, Quincke bevel type, 20G*50mm
9.	FS2075Q0	Anaesthesia needle, Quincke bevel type, 20G*75mm
10.	FS2090Q0	Anaesthesia needle, Quincke bevel type, 20G*90mm
11.	FS2190Q0	Anaesthesia needle, Quincke bevel type, 21G*90mm
12.	FS2238Q0	Anaesthesia needle, Quincke bevel type, 22G*38mm
13.	FS2250Q0	Anaesthesia needle, Quincke bevel type, 22G*50mm
14.	FS2275Q0	Anaesthesia needle, Quincke bevel type, 22G*75mm
15.	FS2290Q0	Anaesthesia needle, Quincke bevel type, 22G*90mm
16.	FS2212Q0	Anaesthesia needle, Quincke bevel type, 22G*120mm
17.	FS2215Q0	Anaesthesia needle, Quincke bevel type, 22G*150mm
18.	FS2375Q0	Anaesthesia needle, Quincke bevel type, 23G*75mm
19.	FS2530Q0	Anaesthesia needle, Quincke bevel type, 25G*30mm
20.	FS2550Q0	Anaesthesia needle, Quincke bevel type, 25G*50mm
21.	FS2575Q0	Anaesthesia needle, Quincke bevel type, 25G*75mm
22.	FS2590Q0	Anaesthesia needle, Quincke bevel type, 25G*90mm
23.	FS2510Q0	Anaesthesia needle, Quincke bevel type, 25G*103mm
24.	FS2512Q0	Anaesthesia needle, Quincke bevel type, 25G*120mm
25.	FS2690Q0	Anaesthesia needle, Quincke bevel type, 26G*90mm
26.	FS2612Q0	Anaesthesia needle, Quincke bevel type, 26G*120mm
27.	FS2790Q0	Anaesthesia needle, Quincke bevel type, 27G*90mm
28.	FS2710Q0	Anaesthesia needle, Quincke bevel type, 27G*103mm
29.	FS2712Q0	Anaesthesia needle, Quincke bevel type, 27G*120mm
30.	FS2290P0	Anaesthesia needle, Pencil bevel type, 22G*90mm
31.	FS2212P0	Anaesthesia needle, Pencil bevel type, 22G*120mm
32.	FS2538P0	Anaesthesia needle, Pencil bevel type, 25G*38mm
33.	FS2590PG	Anaesthesia needle, Pencil bevel type, 25G*90mm
34.	FS2690P0	Anaesthesia needle, Pencil bevel type, 26G*90mm

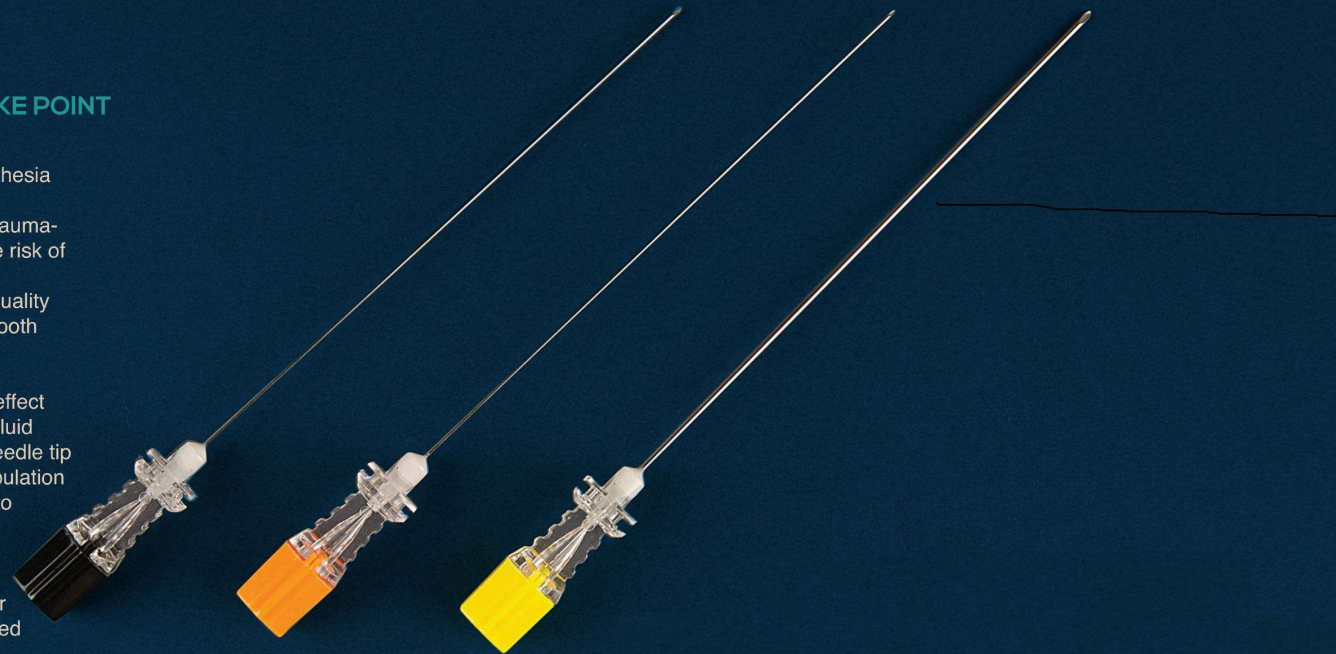
SPINAL NEEDLE EDGE

SPINAL NEEDLES QUINCKE POINT

The spinal needle combines various advantages such as precise application and flexibility. The needle guides excellently and, due to its inner needle, prevents a biopsy effect. This needle is also suitable for lumbar puncture for liquor pressure measurement and for occipital aspiration.

SPINAL NEEDLES WITH QUINCKE POINT DESCRIPTION

- Spinal needles are used for spinal anaesthesia or diagnostic puncture of the spinal canal
- Quincke tip with double bevel enables atraumatic puncture of the dura and minimises the risk of post - spinal headache
- Spinal needle manufactured from high - quality steel, with a thin - walled cannula; the smooth needle surface enables easy, atraumatic puncture
- Transparent needle hub with magnifying effect enables quick detection of cerebrospinal fluid backflow and precise positioning of the needle tip
- Needle hub is designed for ease of manipulation
- Mandrel grip is colour - coded according to needle size
- Range includes spinal needles with short guide needle for puncturing dense tissue and for insertion of the spinal needle in the required direction



MEDICAL GRADE MATERIALS SAFETY TESTED

Needles - High Quality Steel
Hub - Polypropylene

QUALITY

Conforms to ISO 7864 standard

PACKAGING

blister/carton
tray/carton

STERILISATION

Ethylene oxide

SHELF LIFE

5 years