

# Sterimedix Ltd

Quality System Document QD 2040 Issue P  
EC Declaration of Conformity

**Sterimedix Ltd.**

## Declaration of Conformity for Anaesthetic Needles and Cannulae

Ref: DOC01

30/05/2018 - Issue 4

### Council Directive 93/42/EEC Concerning Medical Devices

The undersigned declares that the product named in this document meets the applicable Council Directive provisions that apply and the CE Mark may be affixed.

<b>General Product Name</b>	Anaesthetic Needles and Cannulae	
<b>Product Reference</b>	<b>Anaesthetic Needles</b> M0275; M0285; M0637; M0638; M0639; M0641; M0641A; M0642; M0642A; M0642B; M0643; SD1275; SD1637; SD5108; SD5109; SD5176; AU1638, AU3511; AU3514 <b>Anaesthetic Cannulae</b> M0278; M0279; AU0025	
<b>Manufacturer</b>	Sterimedix Ltd 1 Madeley Road, North Moons Moat, Redditch Worcestershire, B98 9NB, UK	
<b>Notified Body</b>	Notified Body 0120 SGS United Kingdom Ltd 202b Worle Parkway, Weston-super-Mare, BS22 6WA	
<b>Intended Use</b>	Surgically invasive device for administering anaesthesia into either the muscle cone, or around the globe, or into the Sub Tenon space, and intended for transient use.	
<b>Sterile</b>	Sterile - EO. Approved by SGS United Kingdom Ltd	
<b>Measuring Function</b>	No	
<b>Conforming to Current Standards</b>	EN 556-1 ISO 594-1, 2 BS EN 980 EN 1041 EN 1707 EN ISO 10993-1, 3, 4, 5, 6, 7, 11 EN ISO 11135-1	EN ISO 11607-1, 2 EN ISO 11737-1, 2 EN ISO 13485 EN ISO 14155-1 EN ISO 14937 EN ISO 14971 EN ISO 15223-1
<b>Classification</b>	Class IIa in accordance with Annex IX Rule 6	
<b>CE Marking</b>	Notified Body and Number: Initial Date of CE Marking: Certified to: Certificate Number: Certificate Issue Date: Certificate Expiry Date:	SGS 0120 21/05/1997 93/42/EEC GB97/9964 12/08/2015 06/02/2020
<b>Assessment Route</b>	By Annex II excluding section 4 and Article 11 of the European Communities Council Directive 93/42/EEC amended by Directive 2007/47/EC, and the application of BS EN ISO 13485:2016.	

This product does not contain human blood derivatives and is not manufactured utilising tissues of animal origin.

Signed  ..... Date 31/5/18 .....

Name: Andrew Ellis

Position: QA/RA Manager