

Sterimedix Ltd

Quality System Document QD 2040 Issue 0
EC Declaration of Conformity

Sterimedix Ltd. Declaration of Conformity for Infusion Cannulae

Ref: DOC06.1

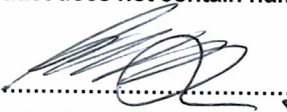
17/01/2019 - Issue 7

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.

General Product Name	Infusion Cannulae	
Product Reference	High Pressure Infusion Cannulae M4461; M4461A; M4462; M4462A; M4469; SD4461; SD4462 Self Retaining Infusion Cannulae M4464; M4465; M4465A; M4467; M4467A; M4468 Trocar Infusion Cannulae 03VI37; 03VI38; M4511; M4516	
Manufacturer	Sterimedix Ltd Unit 1 Madeley Road, North Moons Moat, Redditch, Worcestershire, B98 9NB, UK	
Notified Body	Notified Body 0120 SGS United Kingdom Ltd 202b Worle Parkway, Weston-super-Mare, BS22 6WA	
Intended Use	Surgically invasive device for Infusing air, balanced salt solution (BSS) or heavy liquids/gases to maintain the form and intraocular pressure within the posterior segment, during vitreoretinal procedures. They are intended for short term or transient use.	
Sterile	Sterile – EO. Approved by SGS United Kingdom Limited	
Measuring Function	No	
Conforming to Current Standards	EN 556-1 ISO 594-1 BS EN 980 EN 1041 EN 1707 EN ISO 9001 EN ISO 10993-1, 3, 5, 7, 11 EN ISO 1135-1	EN ISO 11607-1, 2 EN ISO 11737-1, 2 EN ISO 13485 EN ISO 14937 EN ISO 14971 EN ISO 15223-1 BS EN 20594-1
Classification	Class IIa in accordance with Annex IX Rule 6	
CE Marking	Notified Body and Number:	SGS 0120
	Initial Date of CE Marking:	21/05/1997
	Certified to:	93/42/EEC
	Certificate Number:	GB97/9964
	Certificate Issue Date:	12/08/2015
	Certificate Expiration Date:	06/02/2020
Assessment Route	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 13485:2012.	

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

Signed  Date 17/1/19
Name Andrew Ellis
Position QA/RA Manager