

Sterimedix Ltd

Quality System Document QD 2040 Issue M
EC Declaration of Conformity

Sterimedix Ltd.

Declaration of Conformity for Trocar Sets for Vitreoretinal Surgery

Ref: DOC17

10/01/2017 - 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.

General Product Name	Trocar Sets for Vitreoretinal Surgery	
Product Reference	M4510; M4515; 03VI17; 03VI18;	
Manufacturer	Sterimedix Ltd 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	A surgically invasive, single use device, which when in situ, provides three entry conduits to the posterior segment of the eye, to facilitate the introduction of various micro surgical ophthalmic instruments (e.g. Vitreoretinal forceps, scissors, fibre optic lighting, cannulae, and infusion cannula). The devices are intended for transient or short term use	
Sterile	Sterile - EO. Approved by SGS United Kingdom Ltd	
Measuring Function	No	
Conforming to Current Harmonised 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 11135-1	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	
Assessment Route	Annex II excluding section 4 and Article 11 of the European Communities Council Directive 93/42/EEC, and the application of BS EN ISO 13485	
CE Marking	Notified Body and Number: SGS 0120 Initial Date of CE Marking: 12/08/2015 Certified to: Directive 93/42/EEC Certificate Number: GB97/9964 Certificate Issue Date: 12/08/2015 Certificate Expiration Date: 06/02/2018	

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

Signed P. MARTIN Date 16/01/2017
Name Pete Martin
Position Quality and Regulatory Manager

