

# Sterimedix Ltd

Quality System Document QD 2040 Issue P  
EC Declaration of Conformity

## Sterimedix Ltd. Declaration of Conformity for Vitreoretinal Handpieces

Ref: DOC12.1

13/10/2017 - Issue 9

### 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** Vitreoretinal Handpieces

**Product Reference** **Vitreoretinal Heavy Liquid Infusion Handpieces**  
M4498;  
**Backflush Aspiration Handpieces**  
M4489; M4489A; M4493; 03CA89; 03CA89A;  
**Silicone Backflush Reservoir**  
M4488A;

**Manufacturer** Sterimedix Ltd  
1 Madeley Road, North Moons Moat, Redditch,  
Worcestershire, B98 9NB

**Notified Body** Notified Body 0120  
SGS United Kingdom Ltd  
202b Worle Parkway, Weston-super-Mare, BS22 6WA

**Intended Use** Non-invasive devices, used in conjunction with a variety of cannulae, for specific infusion and aspiration functions during retinal procedures.

**Sterile** Sterile – EO. Approved by SGS United Kingdom Ltd

**Measuring Function** No

**Conforming to Current Standards** EN 566-1 EN ISO 11607-1, 2  
ISO 594-1,2 EN ISO 11737-1, 2  
BS EN 980 EN ISO 13485  
EN 1041 EN ISO 14155-1  
EN 1707 EN ISO 14937  
EN ISO 9001 EN ISO 14971  
EN ISO 10993-1, 3, 4, 5, 6, 7, 11 EN ISO 15223-1  
EN ISO 11135-1

**Classification** Class IIa in accordance with Annex IX Rule 2

**CE Marking** Notified Body and Number: SGS 0120  
Initial Date of CE Marking: 21/05/1997  
Certified to: Directive 93/42/EEC  
Certificate Number: GB97/9964  
Certificate Issue Date: 13/09/2017  
Certificate Expiry 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



Name: Tom Parrott

Date 13.10.2017

Position: Plant Manager

