

# Sterimedix Ltd

Quality System Document QD 2040 Issue 0  
EC Declaration of Conformity

## Sterimedix Ltd. Declaration of Conformity for Vitreoretinal Handpieces

Ref: DOC12.2

20/12/2018 - 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.

<b>General Product Name</b>	Vitreoretinal Handpieces	
<b>Product Reference</b>	<b>Handpieces with Cannulae</b> M4480; M4481; M4491; M4492; M4494; M4495; M4496; M4497; M4500; M4501; M4502; M4503; M4504; M4505; M4507; M4509; M4530; M4531; M4532; M4533	
<b>Manufacturer</b>	Sterimedix Ltd 1 Madeley Road, North Moons Moat, Redditch, Worcestershire, B98 9NB	
<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 devices for passive aspiration during retinal surgery, 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 566-1 EN 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 EN ISO 20594-1
<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 Issue Date: Certificate Expiration Date:	SGS 0120 06/02/2006 Directive 93/42/EEC 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: 2012.	

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

Signed



Date

20/12/18

Name: Andrew Ellis

Position: QA/RA Manager