

Sterimedix Ltd

Quality System Document QD 2040 Issue P
EC Declaration of Conformity

Sterimedix Ltd.

Declaration of Conformity for Refractive Cannulae

Ref: DOC10

30/05/2018 - Issue 5

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	Refractive Cannulae	
Product Reference	Refractive Cannulae M2801; M2802; M2804; M2817; M2819; M2822; M2824; M3913; M3914; SD5250;	
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	For use after ablation, to wash particulate away from either the Anterior or Posterior sides of the flap, and from the stromal bed.	
Sterile	Sterile - EO. Approved by SGS United Kingdom Ltd	
Measuring Function	No	
Conforming to Current Standards	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
Classification	Class IIa in accordance with Annex IX Rule 6	
CE Marking	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
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 13485:2016.	

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