Sterimedix Ltd

Quality System Document QD 2040 Issue P
EC Declaration of Conformity

Sterimedix Ltd.
Declaration of Conformity for Cystotomes

Ref: DOC04	30/05/2018 - 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	Cystotomes
Product Reference	**Straight Irrigating Cystotome** M3610A; M3612; **Formed Irrigating Cystotomes** M3001; M3602; M3610; M3610B; M3610C; M3610S; M3615; M3615A; M3617; M3626; M3626A; M3627: M3627A; M3628; M3628A; M3629; M3629A; M3630; SD1610; SD1618; SD5004; AU1610; AU3009 **Formed Capsularhexis Cystotomes** M3000D; M3000E; M3000F; M3000G; SD4804; SD5042;
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	Surgically invasive device for Capsularhexis, Intercapsular, Endocapsular, or can opening capsulotomies. The formed variants are shaped to conform to the crystalline lens, with the shorter curved models being suited to patients with deeper set eyes or smaller pupils, and are intended for transient use.
Sterile	Sterile - EO. Approved by SGS United Kingdom Limited
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: 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 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 13485:2016.

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