# Sterimedix Ltd

**Quality System Document QD 2040 Issue M**
**EC Declaration of Conformity**

**Sterimedix Ltd.**
**Declaration of Conformity for Scleral Markers**

| Ref: DOC14 | Issue 5 |
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## 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.

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|---|---|
| **General Product Name** | Scleral Markers |
| **Product Reference** | **Scleral Markers**<br>M7500; 7500NS;<br>**Scleral Incision Templates**<br>M7510; 7510NS; |
| **Manufacturer** | Sterimedix Ltd<br>1 Madeley Road, North Moons Moat, Redditch<br>Worcestershire, B98 9NB, UK |
| **Notified Body** | Notified Body 0120<br>SGS United Kingdom Ltd<br>202b Worle Parkway, Weston-super-Mare, BS22 6WA |
| **Intended Use** | Invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use. |
| **Sterile** | Sterile - EO. Approved by SGS United Kingdom Ltd |
| **Measuring Function** | Yes |
| **Conforming to Current Harmonised Standards** | EN 556-1<br>BS EN 980<br>EN 1041<br>EN ISO 9001<br>EN ISO 10993-1<br>EN ISO 11135-1<br>EN ISO 11607-1, 2<br>EN ISO 11737-1, 2<br>EN ISO 13485<br>EN ISO 14937<br>EN ISO 14971<br>EN ISO 15223-1 |
| **Classification** | Class IM/IS in accordance with Annex IX Rule 5 |
| **CE Marking** | Notified Body and Number: SGS 0120<br>Initial Date of CE Marking: 14/05/2013<br>Certified to: 93/42/EEC<br>Certificate Number: GB13/88796 and GB13/88797<br>Certificate Issue Date: 12/08/2015<br>Certificate Expiry Date: 06/02/2020 |
| **Assessment Route** | By Annex V 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** 13/11/18

**Name: Andrew Ellis**

**Position: QA/RA Manager**