



Setting Standards
Across Seven Sectors

E.E.C Declaration of Conformity

Steroplast Healthcare Ltd, the manufacturer, declare that the medical devices stated within this document:

| Product | Description | Steroplast Code |
|-----------------|----------------------|-----------------|
| Eye / Woundwash | 20ml Eye / Woundwash | 1400W |
| | | |
| | | |

Have been classified as Class IIa (Annex IX Rule 4), and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC and are in conformity with the national standards transposing harmonised standards EN ISO 14971:2012, ISO 15223:2016, and EN ISO 13485:2016, and are subject to the procedure set out in Annex V of the Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House, Noorderlaan 87 2030, Antwerp, Belgium. Certificate number GB19/964596.

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Operations Director – Afzal Ramzan

Signed –

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