

## E.E.C Declaration of Conformity



Steroplast Healthcare Ltd hereby declare that the devices described hereafter:

| Product            | Description                           | Steroplast Code |
|--------------------|---------------------------------------|-----------------|
| Sterochef Plasters | 100 Assorted in Divider Tray          | 5638S           |
| Steroflex Plasters | Finger Extension 15cm x 2xm Box of 50 | 6230S           |
| Steroflex Plasters | 10 Assorted                           | 6235            |

Have been classified as Class Is (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, BS EN ISO 15223-1:2016, ISO 11135-1:2014 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.

Steroplast Healthcare Ltd, Alpha Point, Bradnor Road, Manchester, M22 4TE  
T: 0044 (0)161 902 3030, F: 0044 (0)161 902 3040, e-mail: [sales@steroplast.co.uk](mailto:sales@steroplast.co.uk)

Operations Director – Afzal Ramzan

Signed –

Date – 24<sup>th</sup> May 2022

Issue 1

