Tristel

EC DECLARATION OF CONFORMITY TO MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC

Legal Manufacturer:	Tristel Solutions Ltd Lynx Business Park, Fordham Road, Snailwell, Cambridgeshire, CB8 7NY United Kingdom
European Representative:	Not Applicable
Product:	**Tristel Fuse for Medical Surfaces – Fragranced** **Tristel Fuse for Medical Surfaces – Unfragranced** Pack size: 40 Sachets
Classification:	Class IIa
Conformity Assessment Route:	Annex II

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.
These products do not contain animal tissue, phthalates or medicinal products nor are such materials used during their manufacture.
The requirements of PPE and that of the Machinery Directive 2006/42/EC do not apply to these products.

This declaration is based upon a review that the specific requirements concerning:

1) A Design file and Full Quality Assurance System compliant to Annex II;
2) Compliance to the Essential Requirements as per Annex I;
3) Quality Assurance procedures in accordance with EN ISO13485:2016
4) The implementation of a systematic procedure for post-market surveillance;

have been satisfactorily fulfilled.

Notified Body:	BSI Group The Netherlands B.V. Say Building, John M.Keynesplein 9, 106 EP Amsterdam, The Netherlands No. 2797 Previous Notified Body: BSI UK (No. 0086)
Certificate(s):	ISO 13485:2016 & EN ISO 13485:2016 Certificate No. MD78322 Annex II CE Certificate No. CE544967
Certificate, Place, Date of Issue:	MD78322, Milton Keynes, 10.09.2018 (First Issued 08.12.2003) CE544967, Amsterdam, 20.12.2018 (First Issued 20.04.2009)

Signature: Steve Garrod

Name: Steve Garrod
Position: Quality Director
Date: 05 MAR 19