Cuxson Gerrard & Company Limited

EC DECLARATION OF CONFORMITY

Cuxson Gerrard & Company Limited declares that the medical device described hereafter as Tofoam (See product Code below) is classified as a Class 1 Non-sterile Medical Device by Rule 1 of Annex IX and are in conformity with the essential requirements Annex 1 and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC

This supports the application of the CE mark to the Tofoam placed on the European market by Cuxson Gerrard & Company Limited.

Although Class 1 non-sterile Medical Devices do not require intervention by a Notified Body, the Cuxson Gerrard & Company Limited ISO13485: 2016 Quality Management system is approved by SGS United Kingdom Limited, Rossmore Business Park, Ellesmere Port, Cheshire CH65 3EN, who have Notified Body status and would be the nominated Body representing Cuxson Gerrard & Company Limited. Certificate No.GB98/13290.

Product Code: TOF 111 Tofoam BX, 18mm - Unit 12

Signed on behalf of Cuxson Gerrard & Company Limited

Mrs Jenny Dent
Quality Assurance Manager

28th October 2020

Cuxson Gerrard & Company Ltd.
125 Broadwell Road, Oldbury,
West Midlands B69 4BF, England

Telephone: 0121-544 7117 Fax: 0121-544 8616
www.cuxsongerrard.com
Registered in England No. 80715