

EC DECLARATION OF CONFORMITY
PROTECTIVE GEL RANGE

Manufacturers Name: Cuxson Gerrard & Co Ltd

Manufacturers Address: 125 Broadwell Road
Oldbury
West Midlands
B69 4BF

SRN (Single Registration Number): IE-AR-000003838

Authorised Representative: Cuxson Gerrard Healthcare Ltd
Unit 3D North Point House
New Mallow Road
Cork T23 AT2P
Ireland

Basic UDI-DI: 5012654ProtectivegelsLH

Name of the Device: Protective Gel Range

Product Code: CHG - Hapla Gel Tube - CHG127, CHG128
Hapla Gel Strip - CHG137, CHG138

Intended Use: The devices are intended to offer symptomatic relief of physical foot disorders and similar conditions, by providing a mechanical barrier which relieves the effects of pressure and friction and or support.

Classification: Class I (Non-sterile)

Conformity Assessment Route: Cuxson Gerrard & Co Ltd uses the following procedure for the CE labelling of their products according to Regulation (EU) MDR 2017/745:

Class I medical devices by Rule 1 of Annex VIII and in conformity with the General Safety and Performance Requirements of Annex I.

This declaration of conformity is issued under the sole responsibility of Cuxson Gerrard & Co Ltd. We hereby declare that the medical device specified above meets the provisions of the Regulation (EU) MDR 2017/745 for medical devices. 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 Ltd, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, who have Notified Body status and would be the nominated Body representing Cuxson Gerrard & Company Limited.

Signed on behalf of Cuxson Gerrard & Company Limited



Mrs J. Dent
Quality Assurance Manager
Date: 15/09/2021

Cuxson Gerrard & Company Ltd.
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