

EC DECLARATION OF CONFORMITY ADHESIVE AND NON-ADHESIVE PADDINGS & STRAPPINGS

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: 5012654Pads&strapsY6

Name of the Device: Adhesive and Non-Adhesive Paddings & Strappings

Product Code: CHI – Chirofix – CHI307, CHI312, CHI314, CHI316
FEL – Hapla Felt – FEL140, FEL142, FEL146
FLE – Hapla Fleecy Foam – FLE240
H.A. Fleecy Foam – FLE300, FLE955
Hapla Fleecy Web – FLE950, FLE970
FOA – Hapla Foam-o-Felt – FOA100B
HAP – Haplaband – HAP211, HAP213, HAP215
MOL – Hapla Moleskin – MOL121
H.A. Moleskin – MOL100
Zopla Molesakin – MOL131, MOL133
PAD – Oval Bunion – PAD109
Round Bunion – PAD541
Round Corn – PAD128
Oval Corn – PAD656
SWA – Hapla Swanfoam – SWA100
H.A. Swanfoam – SWA300
TOF – Tofoam – TOF700, TOF701, TOF710, TOF711, TOF720, TOF721, TOF730, TOF731

Intended Use: The devices are simple paddings and strapping materials intended to provide relief from the effects of friction, pressure 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 meet 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: 06/12/2022