

**EC DECLARATION OF CONFORMITY**  
**SULCI PROTECTOR 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: 5012654SulciprotectorQA

Name of the Device: Sulci Protectors Range

Product Code: SUL – Sulci Protectors – SUL110, SUL115, SUL120

Intended Use: The devices are intended to be used for straightening, mending and shaping the side edges of the nail and for cushioning the nail against irritation or inflammation from the nail wall.

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: 06/12/2022

Cuxson Gerrard & Company Ltd.  
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