

EC - Declaration of Conformity

We, Systagenix Wound Management Ltd (of Gargrave, North Yorkshire, BD23 3RX, UK and with an EU Authorised Representative located at KCI Manufacturing, IDA Business & Technology Park, Dublin Road, Athlone, Co. Westmeath, Ireland) being the manufacturer/distributor within the European Economic Area of the following Class Is (sterile) device,

ADAPTIC® Digit Non-Adhering Digit Dressing

product codes as detailed in product specification ADAPTICA01 (rev 33)

[GMDN Code and Term: 46855: Wound – non-adherent dressing, permeable, non-antimicrobial]

declare that the above are in conformity with the applicable provisions of Council Directive 93/42/EC as amended by European Directive 2007/47/EC, subject to the conformity assessment procedures laid down in Annex I and Annex VII.

For aspects specifically related to sterilisation, Annex II (excluding section 4), is used, under the supervision of the BSI, a Notified Body authorized by the Dutch Competent Authority, and carrying the Notified Body Number 2797 (traceable to 0086).

Margaret Bessenbach Director Regulatory Affairs

December 21, 2021

Date

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