2: Systagenix

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CDS Controlled Copy

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 IIb device.

ACTISORB® Activated Charcoal Dressing ACTISORB® SILBERFREI Activated Charcoal Dressing ODOLOCK[™] Activated Charcoal Dressing

product codes as detailed in product specification FPS-ACTISORB (Rev 06)

[GMDN Code and Term: 44897: odour-absorbent dressing, non-antimicrobial]

declare that the above is 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 II (excluding section 4), under the supervision of BSI, a Notified Body authorized by the Dutch Competent Authority, and carrying the Notified Body Number 2797 (traceable to 0086).

Harald Ceschinski Manager RA, QMS and QC

764 May 2021 Date



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