MEDICAL DEVICE DIRECTIVE DESIGN DOSSIER

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 III Medical Device:

INADINE® PVP-I Non Adherent Dressing

(all product codes as detailed in Product Specification:INADINEA04 rev 28)

[GMDN Code and Term: 47203 – Wound-nonadherent dressing, permeable, antimicrobial]

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

This Declaration has been made on the basis of EC Design Examination Certificate Number CE 552032 issued by BSI 25th May 2021, a Notified Body authorised by the Dutch Competent Authority, and carrying the Notified Body number 2797 (traceable to 0086).

Margaret Bessenbach

Margaret Bessenbach
Manager Regulatory Affairs and Quality EMEA

June 10, 2021
Date

For Internal Use Only:
Document Name: RS005F2. Rev 9
SDD01/41&43/RV01