

Document name (#): TPL0010498, rev 06

STF14 Rev 18.0

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,

ADAPTIC® Non-Adhering Dressing

product codes as detailed in product specification ADAPTICA07 (rev 26)

[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 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).

Margaret Bessenbach

Manager Regulatory Affairs and Quality EMEA

October 8, 2020

