bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 56172**

Issued To: **ConvaTec Limited**
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile wound management and drainage accessories, sterile airways management accessories, sterile applicator nozzles, sterile suction sets and tubing, sterile urinary collection systems and accessories, sterile ostomy products and accessories, sterile catheter, cannula and accessories (excluding intravascular, epidural and spinal), sterile securement devices, sterile umbilical cord clamp cutters and sterile intra-abdominal pressure monitoring devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2000-12-22** Date: **2018-10-23** Expiry Date: **2023-10-20**

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