

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 00364  
**Issued To:** **ConvaTec Limited**  
**First Avenue**  
**Deeside Industrial Park**  
**Deeside**  
**Flintshire**  
**CH5 2NU**  
**United Kingdom**

In respect of:

**The design, development and manufacture of sterile wound management dressings (incorporating alginate, hydrogel, foam, fibrous hydrocolloid, porcine gelatin based hydrocolloid and odour-absorbing technologies), sterile medicated wound dressings, sterile wound irrigation devices, sterile ostomy, non-sterile faecal incontinence systems; sterile catheters, cannulae and accessories (excluding intravascular, epidural and spinal); sterile suction sets, sterile gastroenterology tubing; sterile and non-sterile urinary drainage systems and accessories; sterile wound drainage systems, sterile surgical disposables; battery powered negative pressure wound therapy pumps and dressings.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-09**

Date: **2021-04-19**

Expiry Date: **2023-10-20**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.