

Certificate



Production Quality Assurance

No. CE 78321

Issued to:

Tristel Solutions Limited
Lynx Business Park
Fordham Road
Snailwell
Newmarket
CB8 7NY
United Kingdom

In respect of:

The manufacture of Tristel Wipes and disinfectant solutions.
Those aspects of Annex V related to metrology in the manufacture of dosing systems.
Those aspects of Annex V related to securing and maintaining the sterility of rinse wipes.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

David Ford, Managing Director, BSI Product Services

First Issued: 8 Dec 2003

Date: 19 Nov 2008

Expiration Date: 12 Dec 2009

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

*raising standards worldwide*TM



List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 78321**
Date: **19 Nov 2008**
Issued to: **Tristel Solutions Limited**
Newmarket
United Kingdom

Subcontractor

Service(s) supplied

CustomPack
A Division of Chequer Foods Limited
Halesfield 14
Telford
Shropshire
United Kingdom
TF7 4QR

Packaging

Medichem International Ltd
Rushenden Road
Queenborough
Kent
United Kingdom
ME11 5HE

Manufacture

Isotron plc
Brunel Close
Drayton Fields Industrial Estate
Daventry
United Kingdom
NN11 8RB

Gamma Sterilization

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor	Service(s) supplied
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Flexible Medical Packaging Ltd Unit 8 Hightown Whitecross Industrial Estate Lancaster United Kingdom LA1 4XS	Packaging
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Product Services

History of Quality Assurance Certificate

Certificate No: CE 78321
Issue Date: 19 November 2008
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Date	Customer Reference	Action
08 December 2003		First Issue
23 June 2004	4564751	Addition of Medichem and Custom Packaging as subcontractors.
13 December 2004		Extension of scope to include the manufacture of disinfectant solutions and dosing systems. ®
10 March 2005		Extension of scope to include 'Those aspects of Annex V related to securing and maintaining the sterility of rinse wipes'. Plus the addition of Isotron, Daventry for Gamma Sterilization.
10 March 2006	4815268	Change in company name from The Tristel Co Ltd to Tristel Solutions Limited. Change in company name and location of packaging subcontractor Custom Packaging Ltd, Hortonwood, Telford, to CustomPack , A Division of Chequer Foods Limited, Halesfield, Telford plus the addition of Adpack Europe Limited, Alderton, as a subcontractor for Packaging.
19 November 2008	7101736	The removal of Adpack & the addition of Flexible Medical Packaging as a significant subcontractor.