

EC Certificate - Full Quality Assurance System

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

No. CE 00424
Issued To: **KeyMed (Medical & Industrial Equipment) Ltd.**
Keymed House
Stock Road
Southend-on-Sea
Essex
SS2 5QH
United Kingdom

In respect of:

The design, development and manufacture of suction pumps, lavage pumps for endoscopic and electrosurgery applications, sterile flushing pump tubing and endoscope disinfection systems.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 January 1995**

Date: **06 April 2016**

Expiry Date: **06 January 2020**

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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.

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List of Significant Subcontractors

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

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Date: **06 April 2016**
Issued To: **KeyMed (Medical & Industrial
Equipment) Ltd.
Keymed House
Stock Road
Southend-on-Sea
Essex
SS2 5QH
United Kingdom**

Subcontractor:	Service(s) supplied
Algram Group Ltd Eastern Wood Road Langage Industrial Estate Plympton, Plymouth Devon PL7 5ET United Kingdom	Manufacture
Pennine Healthcare / Ivor Shaw Ltd City Gate London Road Derby DE24 8WY United Kingdom	Manufacture
Riverside Medical Packaging Co Ltd Riverside House Newmarket Drive Derbyshire DE24 8SW United Kingdom	Packaging

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Subcontractor:

Service(s) supplied

Synergy Health Sterilisation UK Ltd
(Synergy Health - AST - Daventry)
Brunel Close
Drayton Fields Industrial Estate
Daventry NN11 8RB
United Kingdom

Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
09 January 1995		Initial Issue
21 July 2003		Name of manufacturer on certificate changed
11 August 1998		Addition of Keymed Manufacturing Division in Sutton Road Southend-on-sea as a separate site
17 May 2000		Addition of Endoscopic insufflators and endoscopic lavage pumps to the scope of certification
17 December 2003		Addition of electrosurgery footswitches to the scope of certification and renewal of certificate.
04 January 2005		Certificate Renewal
07 January 2010	7296944	Certificate Renewal
January 2010	7480033	Addition of sterile flushing pump tubing to the scope, and addition of Riverside Medical Packaging Ltd, Riverside House, Newmarket Drive, Derby DE24 8SW, Isotron Ltd, Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB and Pennine Healthcare/Ivor Shaw Ltd, City Gate, London Road, Derby, Derbyshire DE24 8WY as subcontractors.

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Date	Reference Number	Action
20 July 2012	7867371	Scope extended to include 'endoscope disinfection systems' Change of subcontractor name from 'Isotron' to 'Synergy Health'. Change of subcontractor name from "Riverside Medical Packaging Ltd" to "Riverside Medical Packaging Co Ltd" Correction to the company name Pennine Healthcare, "Healthcare" changed to "Healthcare"
19 December 2013	8083335	Addition of "Algram Group Ltd" as subcontractor for manufacture.
24 December 2014	8242351	Certificate Renewal, Scope reduction to remove Endoscopic insufflators.
06 April 2016	8504450	Scope extended to include "electrosurgery applications" for lavage pumps.

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