

# 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.**  
**Those aspects of Annex II concerned with securing and maintaining sterile conditions of ET sterilised holder for endotherapy devices.**

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: **1995-01-09**

Date: **2020-12-09**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

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.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 00424

Issued To:

**KeyMed (Medical & Industrial  
Equipment) Ltd.  
Keymed House  
Stock Road  
Southend-on-Sea  
Essex  
SS2 5QH  
United Kingdom**

NBOG Code	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
MD 1107	Disinfection system	The Olympus TD-20 Manual Disinfector has been designed to facilitate the cleaning and disinfection of compatible Olympus endoscopes and their accessories in accordance with their instruction for use.
<b>Class IIa</b>		
MD 1104	Suction Pump	N/A
MD 1104	Flushing Pump	N/A
MD 0101	Tubing set for Suction Pump (single use)	N/A
MD 0101	Tubing set for Suction Pump (reusable)	N/A
MD 0101	Tubing set for Flushing Pump (single use)	N/A
MD 0101	Instrument Channel Adaptor	N/A
<b>Class Is</b>		
MD 0101	ET Sterilised Holder	N/A

First Issued: **1995-01-09**

Date: **2020-12-09**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 00424**  
Date: **2020-12-09**  
Issued To: **KeyMed (Medical & Industrial  
Equipment) Ltd.  
Keymed House  
Stock Road  
Southend-on-Sea  
Essex  
SS2 5QH  
United Kingdom**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Algram Group Ltd Eastern Wood Road Langage Industrial Estate Plympton Plymouth PL7 5ET United Kingdom	<b>Manufacture</b>
Ivor Shaw Limited trading as Pennine Healthcare 300 City Gate London Road Derby DE24 8WY United Kingdom	<b>Manufacture</b>
Olympus Europa SE & CO. KG Wendenstrasse 14-20 Hamburg 20097 Germany	<b>EU Representative</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 00424**  
Date: **2020-12-09**  
Issued To: **KeyMed (Medical & Industrial Equipment) Ltd.**  
**Keymed House**  
**Stock Road**  
**Southend-on-Sea**  
**Essex**  
**SS2 5QH**  
**United Kingdom**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
RAUMEDIC AG Hermann-Staudinger-Strasse 2 Helmbrechts 95233 Germany	<b>Manufacture</b>
Riverside Medical Packaging Company Ltd. Newmarket Drive Derby DE24 8SW United Kingdom	<b>Packaging</b>
Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	<b>Radiation (Gamma Sterilization)</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 00424**  
Date: **2020-12-09**  
Issued To: **KeyMed (Medical & Industrial  
Equipment) Ltd.  
Keymed House  
Stock Road  
Southend-on-Sea  
Essex  
SS2 5QH  
United Kingdom**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	<b>ETO Sterilization</b>
Synergy Health Radeberg GmbH Juri-Gagarin-Strasse 15 Radeberg 01454 Germany	<b>Radiation (E Beam Sterilization) Radiation (Gamma Sterilization)</b>
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	<b>Radiation (E Beam Sterilization) Radiation (Gamma Sterilization)</b>

...making excellence a habit.™



# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 00424**  
Date: **2020-12-09**  
Issued To: **KeyMed (Medical & Industrial Equipment) Ltd.**  
**Keymed House**  
**Stock Road**  
**Southend-on-Sea**  
**Essex**  
**SS2 5QH**  
**United Kingdom**

**Subcontractor:**

**Service(s) supplied**

---

Synergy Health Sterilisation UK Ltd  
Roydsdale Way  
Euroway Industrial Estate  
Bradford  
BD4 6SE  
United Kingdom

**Radiation (Gamma Sterilization)**

---

Synergy Health Sterilisation UK Ltd  
Marcus Close  
Tilehurst  
Reading  
RG30 4EA  
United Kingdom

**Radiation (Gamma Sterilization)**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00424**  
 Date: **2020-12-09**  
 Issued To: **KeyMed (Medical & Industrial  
 Equipment) Ltd.  
 Keymed House  
 Stock Road  
 Southend-on-Sea  
 Essex  
 SS2 5QH  
 United Kingdom**

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.

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00424**  
 Date: **2020-12-09**  
 Issued To: **KeyMed (Medical & Industrial  
 Equipment) Ltd.  
 Keymed House  
 Stock Road  
 Southend-on-Sea  
 Essex  
 SS2 5QH  
 United Kingdom**

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.
22 March 2019	7778863	Administrative Subcontractor Service wording update from 'Sterilization' to 'Gamma Sterilization, E-Beam Sterilization, ETO Sterilization & Moist Heat Sterilization' for Synergy Health Sterilization UK Ltd, Daventry NN11 8RB, UK. Traceable to NB 0086.



# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00424**  
 Date: **2020-12-09**  
 Issued To: **KeyMed (Medical & Industrial  
 Equipment) Ltd.  
 Keymed House  
 Stock Road  
 Southend-on-Sea  
 Essex  
 SS2 5QH  
 United Kingdom**

Date	Reference Number	Action
22 March 2019	3000174	Addition of: Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Bradford), Roydsdale Way, Euroway Industrial Estate, Bradford, BD4 6SE, UK; Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Reading), Marcus Close, Tilehurst, Reading, Berkshire, RG30 4EA, UK; Synergy Health Radeberg GmbH, Juri-Gagarin-Strasse 15, 01454 Radeberg, Germany; Sterigenics UK Ltd, Cotes Park Lane, Somercotes, Alfreton, DE55 4NJ, UK; Sterigenics UK Limited, Plot 13a, Seymour Link Road, Markham Vale, Chesterfield, S43 3FG, UK; RAUMEDIC AG, Hermann-Staudinger-Strasse 2, Helmbrechts, 95233, Germany. Addition of product table.
16 December 2019	9768656	Certificate Renewal. Changes to subcontractor address and services for: Algram Group Ltd, Ivor Shaw Limited trading as Pennine Healthcare, Riverside Medical Packaging Company Ltd., Sterigenics UK Limited- Chesterfield, Sterigenics UK Ltd- Alfreton, Synergy Health Rademberg GmbH, Synergy Health Sterilisation UK Ltd- Daventry, Synergy Health Sterilisation UK- Bradford, Synergy Health Sterilisation UK- Berkshire.
02 September 2020	3223731	Scope extended to include Class Is device, ET Sterilised Holder for endotherapy devices. Addition of ET sterilised holder to the device table.

# EC Certificate - Full Quality Assurance System Certificate History

**Certificate No:** CE 00424  
**Date:** 2020-12-09  
**Issued To:** **KeyMed (Medical & Industrial Equipment) Ltd.**  
**Keymed House**  
**Stock Road**  
**Southend-on-Sea**  
**Essex**  
**SS2 5QH**  
**United Kingdom**

Date	Reference Number	Action
Current	3299066	Addition of EU Representative Olympus Europa SE & CO. KG, Wendenstrasse 14-20, Hamburg, 20097, Germany.