

EC Certificate - Production Quality Assurance

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

No. CE 95084
Issued To: **First Water Limited**
Hilldrop Lane
Ramsbury
Marlborough
SN8 2RB
United Kingdom

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of hydrogel adhesives for sacral seals, adhesive gel patches in Negative Pressure Wound Therapy and as fixatives for dressings and tubing.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2005-04-18**

Date: **2019-05-01**

Expiry Date: **2022-07-29**

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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.

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Supplementary Information to CE 95084

Issued To:

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Number	Device Name	Intended purpose per IFU
Class Is		
NBOG code: MD0301/MDS7006	Sterile Adhesive Gel Strip/Patch	The Adhesive Gel Strip/Patch may be used to assist with seal integrity and/or securing fixtures in position at the wound site.

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Page 2 of 2

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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.

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Systagenix Wound Management Limited Gargrave North Yorkshire BD23 3RX United Kingdom	Gamma Irradiation
Medico Electrodes Ltd. Unit 20a, Hawkes Drive Heathcote Industrial Estate Warwick CV34 6LX United Kingdom	Manufacture
Steris Applied Sterilization Technologies Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Gamma Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 95084**
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Date	Reference Number	Action
18 April 2005		First issue.
10 August 2007		Reissue to extend the expiry date for a further two years to expire at the same time as CE 60988.
19 March 2008	7163576	Rewording of scope.
06 August 2012	7856891	Change of name of significant subcontractor Isotron Ltd, Swindon SN2 8XS to Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon). Certificate renewal.
20 September 2013	8029258	Addition of significant subcontractor First Water Heathcote Ltd for the activity of manufacture.
08 August 2017	8727115	Certificate renewal. Administrative update to company name of manufacturing subcontractor from Synergy Health Sterilisation UK Ltd (Swindon) to STERIS Applied Sterilization Technologies providing Gamma sterilisation, and from First Water Heathcote Limited to Medico Electrodes Ltd.
12 March 2019	7779301	Traceable to NB 0086.

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Page 1 of 2

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Date	Reference Number	Action
Current	9754045	Addition of significant subcontractors: Systagenix Wound Management Limited (Gargrave, UK) Addition of product table

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Page 2 of 2

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