

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 60988**  
**Issued To:** **First Water Limited**  
**Hilldrop Lane**  
**Ramsbury**  
**Marlborough**  
**SN8 2RB**  
**United Kingdom**

In respect of:

**The design, development and manufacture of sterile hydrogel, foam, and hydrogel-hydrocolloid wound 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: **2002-07-30**

Date: **2019-05-01**

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

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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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## Supplementary Information to CE 60988

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
GMD No : Not assigned. NBOG Code: D0301/MDS7006	Sterile Hydrogel Based Wound Dressings	Dressing may be used for the management of chronic wounds, on painful wounds and skin conditions such as leg ulcers, radiation therapy damage, burns and scalds. It may be used on low-exuding and non-exuding wounds to assist in autolytic debridement by hydration of necrotic and sloughy tissue and for absorption of exudate. It may be used on moderately exuding wounds, although in such cases it may be preferable to cut the dressing to fit within the wound margins. The dressing can be used on contaminated and colonised wounds. It may be used with secondary dressings where appropriate. Dressings can be used under compression.
GMD No : Not Assigned. NBOG Code: MD0301/MDS7006	Sterile Foam Based Wound Dressings	Used on moderately to heavily exuding wounds, including chronic wounds, such as diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), pressure ulcers / sores (partial and full thickness), 1st and 2nd degree partial thickness burns, donor sites, and traumatic and surgical wounds.

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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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Number	Device Name	Intended purpose per IFU
GMD No : Not Assigned. NBOG Code: MD0301/MDS7006	Hydrogel Hydrocolloid Hybrid (HHH)	Intended for dry and low exuding acute wounds including pressure ulcers, venous leg ulcers, arterial ulcers and diabetic foot ulcers, skin donor sites, post-operative surgical wounds, superficial and partial thickness burns, lacerations and abrasions. Can be used in dry to low exuding wounds. The wound should be monitored and the frequency of dressing changes should be increased accordingly.
<b>Class IIa</b>		
NBOG code : MD0301/MDS7006	Sterile Hydrogel Based Wound Dressings	Moist Wound Healing Dressings are intended to come into contact with injured skin and are principally intended to manage the micro-environment of injured skin by providing a moist wound healing environment by providing moisture balance by donating and absorbing water.
NBOG code : MD0301/MDS7006	Sterile Hydrogel Based Blister and Burn Dressings	Blister and Burns Dressing are intended to come into contact with injured skin and are principally intended to manage the micro-environment of injured skin by providing a moist wound healing environment by providing moisture balance by donating and absorbing water.
NBOG code : MD0301/MDS7006	Sterile Hydrogel Soothing Pads	The Hydrogel Soothing Pad aims to provide instant relief from sore nipples by attaching to the skin as a protective, cooling cushion. They support the healing process by providing moisture and keeping the skin smooth.

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# 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:

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Date: **2019-05-01**  
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**Subcontractor:**

**Service(s) supplied**

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Medico Electrodes Ltd.  
Hawkes Drive  
Heathcote Industrial Estate  
Warwickshire  
CV34 6LX  
United Kingdom

**Manufacture**

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STERIS Applied Sterilization Technologies  
(Formerly Synergy Health Applied Sterilization Technologies)  
Moray Road,  
Elgin Industrial Estate  
Swindon  
SN2 8XS  
UK

**Gamma Sterilization**

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**Subcontractor:**

**Service(s) supplied**

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Synergy Health Sterilisation UK Ltd  
(Synergy Health - AST - Reading)  
Marcus Close  
Tilehurst, Reading  
Berkshire  
RG30 4EA  
United Kingdom

**Gamma Sterilization**

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Systagenix Wound Management Limited  
Gargrave  
North Yorkshire  
BD23 3RX  
United Kingdom

**Gamma Irradiation**

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
30 July 2002		First Issue.
10 August 2007	7005377	Certificate renewal and reissue in new certificate format
08 September 2010	7460732	Extension to scope to include hydrogel-hydrocolloid wound dressings and removal of the word "based" from certificate scope. Addition of significant subcontractor Isotron Limited Reading for the activity of Gamma Sterilization
07 February 2011	7466226	Extension of scope to include foam wound dressings
25 January 2012	7766990	Extension to scope to include chest seal dressings. Addition of significant subcontractor BDK for the activity of manufacture
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). Change of name of significant subcontractor Isotron Ltd, Reading RG30 4EA to Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Reading). Certificate renewal.
28 March 2013	7969895	Extension to scope to include alginate hydrogel composite dressings.
20 September 2013	8029258	Addition of significant subcontractor First Water Heathcote Ltd for the activity of manufacture.

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Date	Reference Number	Action
05 April 2016	8359681	Extension to scope to include silicone adhesive wound dressings. Addition of significant sub-contractor Synergy Health for ETO sterilization. Administrative update to company name of manufacturing sub-contractor from First Water Heathcote Limited to Medico Electrodes Ltd.
08 August 2017	8727296	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.
11 March 2019	8907986	Scope reduction to remove "alginate hydrogel composite dressings, silicone adhesive wound dressings and hydrogel chest seals". Removal of BDK Industrial Products Ltd, Synergy Health Sterilisation UK Ltd (1 Alpha Court) and Granton Medical Limited as significant subcontractors.
12 March 2019	7779301	Traceable to NB 0086.
Current	9754045	Addition of significant subcontractor: Systagenix Wound Management Limited (Gargrave, UK). Addition of product table.