

EC Certificate - Full Quality Assurance System

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

No.

CE 554803

Issued To:

**Water-Jel Technologies LLC
50 Broad Street
Carlstadt
New Jersey
07072
USA**

In respect of:

The design and manufacture of water-based gel products for emergency first aid burns comprising: Emergency First Aid Blankets (preserved), Gels for Burns (preserved), and Burn Dressings (Sterile)

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: **2010-04-22**

Date: **2020-05-31**

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

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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 554803

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 0301	Hydrogel Dressing (sterile)	For use in a burn emergency
MD 0301	Hydrogel Blanket (non-sterile)	Emergency first-aid burn care
MD 0303	Hydrogel gel (non-sterile)	For use on minor burns and scalds

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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.

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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
Isomedix Operations, Inc 9 Apollo Drive Whippany New Jersey 07981 USA	Radiation (Gamma Sterilization)
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	Radiation (Gamma Sterilization)
Water-Jel Europe 3 & 4 The Mead Business Centre Mead Lane Hertford Hertfordshire SG13 7BJ United Kingdom	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
22 April 2010	7444010	First issue, transfer from another Notified Body.
17 August 2011	7716182	Addition of new subcontractor, Steris Isomedix Services, NY for the activity of Gamma Sterilization. Address update for EU Representative, Water-Jel Europe.
29 January 2014	8025183	Administrative update to scope to include development. Scope extension to include gels and lotions for the treatment of radiation burns.
24 April 2015	8330785	Certificate renewal.
13 February 2019	7781378	Traceable to NB 0086.
Current	3078291	Certificate renewal Addition of supplementary information table. Removal of gels and lotions for the treatment of radiation burns from the scope of certification. Name change for Steris Corporation Isomedix Services, NY and Steris Isomedix Services, Inc. to Isomedix Operations, Inc. Removal of "development" from scope expression.