By Royal Charter

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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Supplementary Information to CE 554803

Issued To:

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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

First Issued: **2010-04-22** Date: **2020-05-31** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 554803**
Date:	**2020-05-31**
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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)**
Safeguard Technologies Ltd. Willow Grove Delgany Co Wicklow A63 XY89 Ireland	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554803**
Date: **2020-05-31**
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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.
31 May 2020	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.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
21 July 2021	3423774	Addition of EU Authorised Representative, Safeguard Technologies Ltd., Ireland. Removal of EU Authorised Representative, Water-Jel Europe.

Inspiring trust for a more resilient world.

21st July 2021

Water-Jel Technologies LLC
50 Broad Street
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 554803	93/42/EEC Annex II excluding Section 4	3423774	Addition of EU Authorised Representative, Safeguard Technologies Ltd., Ireland. Removal of EU Authorised Representative, Water-Jel Europe.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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