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

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**
Issued To: **Water-Jel Technologies LLC**
50 Broad Street
Carlstadt
New Jersey
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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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554803**
Date: **2020-05-31**
Issued To: **Water-Jel Technologies LLC**
50 Broad Street
Carlstadt
New Jersey
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USA

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
Carlstadt
New Jersey
07072
USA

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

BSI Group The Netherlands B.V.
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John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
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Water-Jel Technologies LLC
5555 Harrisburg Industrial Park Drive
Harrisburg
North Carolina
28075
USA

17th June 2024

Notified Body Confirmation Letter
Reference: EU2023-607/889209

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Water-Jel Technologies LLC
5555 Harrisburg Industrial Park Drive
Harrisburg,
North Carolina
28075
USA
SRN Number: US-MF-000031537

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Hydrogel Dressing (sterile) **Basic UDI-DI: 074357DRESSINGS001P9**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 554803 Expiry date: 26-May-2024 BSI NL NB# 2797
Hydrogel Blanket (non-sterile) **Basic UDI-DI: 074357BLANKET001JH**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 554803 Expiry date: 26-May-2024 BSI NL NB# 2797
Hydrogel gel (non-sterile) **Basic UDI-DI: 074357GEL001TD**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 554803 Expiry date: 26-May-2024 BSI NL NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	Choose an item.	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/06/17	Initial issue