Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Water-Jel Technologies, LLC
Manufacturer address and contact details	5555 Harrisburg Industrial Park Dr. Harrisburg, NC 28075
Single Registration Number (SRN) (if available)	US-MF-000031537

Authorised Representative name (if applicable)	Safeguard Technologies Ltd.
Authorised Representative address and contact details	Willo Grove Delgany, Co Wicklow, A63 XY89 Ireland
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	BSI
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 554803
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26
End date of extended validity/transition period	2027-12-31

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Head Office
Water-Jel Technologies, LLC
5555 Harrisburg Industrial Park Blvd.
Harrisburg, NC 28075, USA

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

■Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ■ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- **Up classified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  Choose one applicable statement:

  - ■ This section is not applicable to Water-Jel Products as there was no up classification relevant to the devices that are CE Marked.
  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  - ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
  - ■ A QMS in accordance with Article 10(9) MDR is in place.
  - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Water-Jel Technologies, LLC
North Carolina May 10, 2024

DocuSigned by:
Kimberly Reed 10-May-2024
7C135BB50D44474...

Kimberly Reed, Director, Quality and Regulatory Affairs

kimberlyr@safeguardmedical.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Hydrogel Dressing (sterile)	CE 554803	2024-05-26	BSI 2797	BSI 2797	2027-12-31	N/A
Hydrogel Blanket (non-sterile)	CE 554803	2024-05-26	BSI 2797	BSI 2797	2027-12-31	N/A
Hydrogel Gel (non-sterile)	CE 554803	2024-05-26	BSI 2797	BSI 2797	2027-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 554803

Issued To:

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

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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By Royal Charter

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:

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)**
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	**Radiation (Gamma Sterilization)**

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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:

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**
Safeguard Technologies Ltd. Willow Grove Delgany Co Wicklow A63 XY89 Ireland	**EU Representative**
Span Packaging Services, LLC d/b/a Multi-Pack Solutions 1301 Perimeter Road Greenville South Carolina 29605 USA	**Manufacture**

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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
07072
USA

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
07072
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.
30 June 2022	3654119	Addition of subcontractors Span Packaging Services, LLC and Isomedix Operations, Inc. (South Carolina).

Inspiring trust for a more resilient world.

30 June 2022

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	3654119	Addition of subcontractors Span Packaging Services, LLC and Isomedix Operations, Inc. (South Carolina).

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,

Graeme Tunbridge
Senior Vice President, Medical Devices