

Medline Industries LP
Three Lakes Drive
Northfield
Illinois
60093
USA

24 Oct 2023

Notified Body Confirmation Letter
Reference: EU2023-607/647436

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:

Medline Industries LP
Three Lakes Drive
Northfield
Illinois
60093
USA
SRN Number: US-MF-000009717

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
Latex Surgical Gloves	Class IIa	N/A	MDD certificate CE 555682, Expiry 26-May-2024; BSI NL NB# 2797
Synthetic Surgical Gloves	Class IIa	N/A	MDD certificate CE 555682, Expiry 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
Excelsior SwabFlush Sterile Luer Access Valve Cap Sets (including prefilled saline syringe) for IV Lines	Class IIa	N/A	MDD Certificate # US19/819943408 Expiry 03-APR-2024; SGS Belgium NV NB# 1639
Excelsior Saline Flush Syringe Sterile 0.9% Saline Flush Syringe for IV lines	Class IIa	N/A	MDD Certificate # US19/819943408 Expiry 03-APR-2024; SGS Belgium NV NB# 1639
Excelsior Sterile Field Flush Sterile 0.9% Saline Flush Syringe for IV lines	Class IIa	N/A	MDD Certificate # US19/819943408 Expiry 03-APR-2024; SGS Belgium NV NB# 1639

Confirmation Letter Revision History

Date	Action
2023/07/14	Initial issue
2023/10/24	Addition of Latex and Synthetic Surgical Gloves

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.

CE 555682

Issued To:

**Medline Industries, Inc.
Three Lakes Drive
Northfield
Illinois
60093
USA**

In respect of:

Manufacture of sterile gauze (x-ray and non-x-ray), lap sponges, wound drain systems, lubricating jelly and surgical gloves.

Manufacture of sterile and non-sterile fluid administration, management, and pressure monitoring devices and associated accessories

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of skin barrier film, examination gloves, bulb syringes, tubing, torque devices, closed systems tubing sets, guidewire introducers, and insertion tools.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2010-01-20**

Date: **2021-04-02**

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

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Page 1 of 3

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.

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.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 555682

Issued To:

Medline Industries, Inc.
Three Lakes Drive
Northfield
Illinois
60093
USA

NBOG codes (s)	Device description	Intended purpose
Class IIa		
MD 0101	Latex Surgical Gloves	N/A for class IIa devices
MD 0101	Synthetic Surgical Gloves (Polyisoprene; Neoprene; Polyisoprene / Neoprene Blend)	
MD 0301	X-ray gauze	
MD 0301	Laparotomy sponge	
MD 0108	Lubricating Jelly	
MD 0106	Wound drain	
MD 0102, MD 0106	Fluid Administration, management and pressure monitoring devices	
Class Is		
MD 0101	Examination Gloves	N/A for Class Is devices

First Issued: **2010-01-20**

Date: **2021-04-02**

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

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Page 2 of 3

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.

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 555682

Issued To:

Medline Industries, Inc.
Three Lakes Drive
Northfield
Illinois
60093
USA

NBOG codes (s)	Device description	Intended purpose
Class Is		
MD 0102	Bulb Syringes	N/A for Class Is devices
MD 0102	Closed systems tubing sets	
MD 0102	Tubing	
MD 0106	Guidewire Introducers	
MD 0106	Insertion Tools	
MD 0106	Torque devices	
MD 0301	Gauze / ABD Pads / Non-woven swabs	
MD 0303	Skin Barrier Film	

First Issued: **2010-01-20**Date: **2021-04-02**Expiry Date: **2024-05-26**

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Page 3 of 3

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.

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.

27 October 2021

Medline Industries, LP
Three Lakes Drive
Northfield
Illinois
60093
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 555682	93/42/EEC Annex V	3558510	<p>Change in legal manufacturer name from Medline Industries, Inc to Medline Industries, LP</p> <p>Change to name of Medline Industries, Inc facilities 10 Glens Falls Technical Park and 700 W. North Shore Drive to Medline Industries, LP</p>

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



Medline Industries, LP
Three Lakes Drive, Northfield, IL 60093

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates), and
- 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	Medline Industries, LP
Manufacturer address	Three Lakes Drive Northfield, IL 60093
Single Registration Number (SRN)	US-MF-000009717

Authorised Representative name	Medline International France SAS
Authorised Representative address	5 Rue Charles Lindbergh, 44110 Châteaubriant, France
Single Registration Number (SRN)	FR-AR-000001814

Notified body name	BSI Group The Netherlands B.V.
Notified body number	2797
Directive Certificate number to which this confirmation is made	CE 555682
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26-MAY-2024
End date of extended validity/transition period	31-DEC-2028

We, as the legal manufacturer, declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, and
- 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:



Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093

➤ **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 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) are 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.

➤ **Upclassified 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



Medline Industries, LP
Three Lakes Drive, Northfield, IL 60093

May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

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 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 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.

In accordance with Regulation (EU) 2023/607 and guidance MDCG 2020-34, notified bodies cannot issue new MDD certificates during the transitional period. Therefore, certificates will be considered valid after the expiration date listed on the certificate until the appropriate date listed in the attached schedule.

Signed for and on behalf of the manufacturer:

Pahola B. Vasquez
Electronically signed by:
Pahola Vasquez-Arrieta
Reason: Approved
Date: Oct 5, 2023 15:50
CDT

Pahola Vasquez, Director Regulatory Affairs
Medline Industries, LP
Three Lakes Drive, Northfield, IL 60093
PVasquez-Arrieta@medline.com

Mitchell Dale
Electronically signed
by: Mitchell Dale
Reason: Approved
Date: Oct 5, 2023
17:12 CDT

Mitchell Dale, Manager Quality Assurance
Medline Industries, LP
Three Lakes Drive, Northfield, IL 60093
MDale@medline.com



Schedule of Devices

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

Identification of the device(s)¹ (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)
Latex Surgical Glove	CE 555682	26-MAY-2024	BSI Group The Netherlands B.V. NB #: 2797	BSI Group The Netherlands B.V. NB #: 2797	31-DEC-2028	Not applicable
Synthetic Surgical Gloves (Polyisoprene; Neoprene; Polyisoprene / Neoprene Blend)	CE 555682	26-MAY-2024	BSI Group The Netherlands B.V. NB #: 2797	BSI Group The Netherlands B.V. NB #: 2797	31-DEC-2028	Not applicable

¹ for devices with 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)