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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

NB 2797

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 <u>NOT</u> 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

NB 2797

Confirmation Letter Revision History

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

NB 2797

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

Date: June 14, 2023
Subject: Regulation (EU) 2023/607 Declaration

To whom it may concern:

Medline Industries, LP and Excelsior Medical, LLC (a Medline company) declare that the conditions of specified in Medical Device (EU) Regulation 2017/745 (MDR) Article 120.3 as amended by Regulation (EU) 2023/607 have been met. Therefore, the extended transitional periods can be applied to the devices as detailed in the table below.

Table 1. Scope

Device Description	Classification (MDR Annex VIII)	MDD Certificate[1]	MDD Cert Original Expiry	New Transition Period End Date
Excelsior SwabFlush®	IIa	US19/819943408 (SGS Belgium NV, NB# 1639)	4/3/2024	12/31/2028
Excelsior Saline Flush	IIa			
Excelsior Sterile Field Flush	IIa			

Excelsior Medical, LLC (a Medline company) declares that following conditions have been met for the devices listed in the table above:

1. The devices continue to comply with Medical Device Directive 93/42/EEC (MDD).
2. There are no significant changes in design or intended purpose.
3. There are no safety concerns. The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Additionally, Medline Industries, LP declares that:

1. The Quality Management System is compliant with MDR in accordance with MDR Article 10(9)[2].
2. An MDR application and contract is in place with the MDR Notified Body, BSI Group The Netherlands B.V. (BSI)[3].
3. Before 26-Septemeber-2024, a written agreement that details the transfer of responsibility for carrying out the appropriate surveillance activities will be signed with the MDR Notified Body.

Processes are in place to ensure the above declaration remains valid, and this declaration will be updated/re-issued based on any data that affects compliance to these conditions.

[1] 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 Table 1).
[2] BSI Audit Reference 3340775.
[3] BSI Contract Number Q398325.

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

Sincerely,

Stephanie Augsburg

Digitally signed by Stephanie Augsburg
DN: cn=Stephanie Augsburg, o=Medline Industries, LP, ou=Regulatory Affairs, email=saugsburg@medline.com, c=US
Date: 2023.06.15 13:39:02 -05'00'

Stephanie Augsburg
Senior Director, Regulatory Affairs
Medline Industries, LP

Renata DiMarco

Digitally signed by Renata DiMarco
DN: cn=Renata DiMarco, ou=Renata.DiMarco@Medline.com, email=Renata.DiMarco@Medline.Com, c=US
Date: 2023.06.15 11:44:35 -04'00'

Renata DiMarco
Director Quality Assurance
Excelsior Medical, LLC
Medline Industries, LP

Attached:
Medical Device Directive 93/42/EEC Certificate # US19/819943408

EC Certificate Full Quality Assurance System: Certificate US19/819943408

The management system of

Excelsior Medical LLC

1933 Heck Avenue 07753 Neptune, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

This certificate is valid from 31 October 2019 until 03 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 08 May 2007.
And first certified by SGS Belgium on 31 October 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 214405

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Excelsior Medical LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Sterile 0.9% Saline Flush Syringe for IV lines. Sterile Luer Access Valve Cap Sets (including prefilled saline syringe) for IV Lines.

Additional facilities

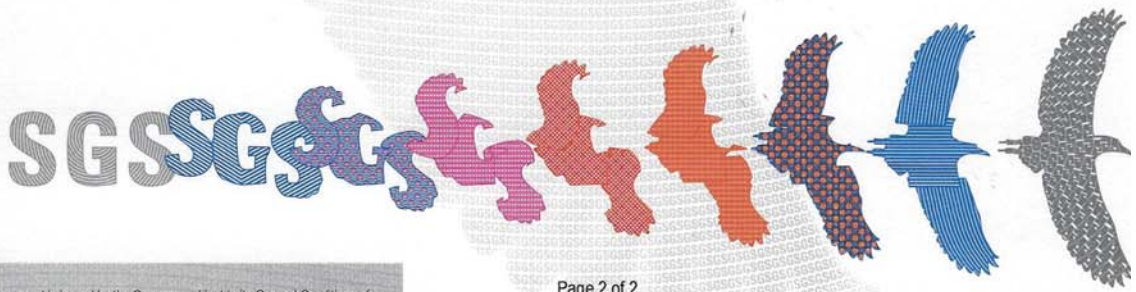
1919 Heck Avenue, Neptune, NJ, 07753, United States

1923 Heck Avenue, Neptune, NJ, 07753, United States

1930 Heck Avenue, Neptune, NJ, 07753, United States

317 Fairfield Road, Freehold, NJ, 07728, United States





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