HENRY SCHEIN®

135 Duryea Road
Melville, New York 11747
Office: 631-843-5500

Manufacturer Self-Declaration of EC Certificate Extension

Regulation (EU) 2023/607 (amending Regulation (EU) 2017/745)

The amendment of the European Medical Device Regulation (MDR) through Regulation (EU) 2023/607 has extended transition periods to provide additional time for manufacturers and EU Notified Bodies to carry out conformity assessments in accordance with the EU MDR 2017/745.

The extension of the transitional period and the concomitant extension of the MDD EC Certificate's validity is done automatically by law, provided the conditions laid down in Article 120 (3c) MDR are fulfilled and, in case of devices for which the relevant certificate has expired before 20 March 2023, the conditions laid in the second subparagraph of Article 120 (2), points (a) or (b).

In accordance with the "*Extension of the MDR Transitional Period and Removal of the 'Sell off' Periods*" guidance document initially issued in March 2023, the European Commission for Health and Food Safety has acknowledged that the manufacturer may demonstrate validity of the certificate by issuing a self-declaration confirming that the conditions for the extension are fulfilled. This document serves as that declaration.

Henry Schein Inc. declares that the medical devices in scope of certification comply with the requirements listed in Regulation (EU) 2023/607 (amending Regulation (EU) 2017/745) as regards the transitional provisions for certain medical devices:

Manufacturer: Henry Schein Inc.
QMS Certificate No.: 7425GB445220616 (EN ISO 13485:2016)
MDD EC Certificate No.: 7425GB415200327 (Directive 93/42/EEC)
Notified Body Number: 0482
MDD EC Certificate Effective Date: 2020-03-27
Original MDD EC Certification Issue Date: 2017-04-07
MDD EC Certificate Expiry Date: 2024-02-02
Classification: Class Is (Per EU MDR 2017/745)
Extended Transition Date: December 31, 2028 (Per EU 2023/607)

To claim compliance to and applicability of the transitional extension per EU 2023/607 Henry Schein Inc. declares that the listed devices comply with the following **Article 120 (3c):**

- The listed medical devices continue to comply with Directives 93/42/EEC, as applicable;
- There have been no significant changes in the design and intended purpose;
- 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;
- Henry Schein Inc. has put in place a quality management system in accordance with EU 2017/745 article 10(9);

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- Henry Schein Inc. lodged an application for MDR Certification with DNV Medcert on August 31, 2020 in accordance with the first subparagraph of Article 4.3 of Annex VII (EU) 2017/745;
- Henry Schein Inc. declares a written agreement has been signed with DNV Medcert on February 1, 2024, in accordance with the second subparagraph of Article 4.3.

Additional evidence of Henry Schein Inc.'s compliance to the above listed conditions is provided in the attached Confirmation Letter, reference number QA-7425, issued by DNV Medcert on February 1, 2024, and last revised May 13, 2024.

Based on the above summary of conditions and attached supporting evidence, Henry Schein Inc. has demonstrated that the requirements listed in Regulation (EU) 2023/607 are met, which automatically extends the validity of Henry Schein Inc. MDD EC Certificate No. 7425GB415200327 to December 31, 2028, by law.

Signed on behalf of Henry Schein Inc.

DocuSigned by:
Tracey Alexander
Signer Name: Tracey Alexander
Signing Reason: I approve this document
Signing Time: 5/20/2024 | 8:26:07 AM PDT
62BECE3FB5FB4C7E915123906E0757E5

5/20/2024

Tracey Alexander
Vice President, Quality Assurance and Regulatory Affairs
tracey.alexander@henryschein.com

Date

Revision	Revision Date	Description
00	02-Feb-2024	Original Issue
01	28-Feb-2024	Added email address to signature.
02	17-May-2024	DNV issued an updated letter which includes the addition of Class I devices that qualify as re-usable surgical instruments to the list. New Certification No., 7425GB454240513.

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Henry Schein Inc.
135 Duryea Road
Melville, NY 11747
U.S.A.

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-03-27**
Expiry date: **2024-02-02**

Report No.: QS-7425FS03F
Process No.: QS – 7425
Certificate No.: 7425GB415200327

Hamburg, 2020-03-27

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 7425
Certificate No.: 7425GB415200327

List of products / product categories included in the scope of certificate

- **Bandages**
- **Gauzes**
- **Gauze balls**
- **Gravity infusion systems (I.V. sets) - sets for drug reconstitution and transfer**
- **Skin Staple Remover**
- **Adhesive Strips**
- **Adhesive wound dressings and IV dressings**
- **Gowns**
- **Surgical gowns**
- **Single use drapes**
- **Surgical adhesive / non adhesive drapes**
- **Vaginal speculums for single use**
- **Surgical Kits**
- **Surgical Marking Pen**
- **Wound and bladder syringe**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

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www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Certification. Medical Only.

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Henry Schein Inc.
135 Duryea Road
11747 Melville New York
United States of America

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date:	**2022-06-16**
Expiry date:	**2025-02-02**

Report No.:	7425FS06F
Procedure No.:	QS – 7425
Certificate No.:	7425GB445220616

Hamburg, 2022-06-16

MEDCERT Certification Body
Lorenz Runge

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body accredited by DAkkS.

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

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Appendix of certificate

Procedure No.: QS – 7425
Certificate No.: 7425GB445220616

Activities and products/services in the scope of certification

Design, manufacture, final inspection, and distribution of
- Disinfectants
- Medical honey based wound dressing
- Oximetry sensors
- Sutures (including non-absorbable polyester sutures)

Manufacture, final inspection, and distribution of
- Dental products
- Medical equipment
- Medical consumables

Locations in the scope of certification

Henry Schein Inc.
135 Duryea Road
11747 Melville New York
United States of America

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2024-05-13

Our reference: QS-7425

Notified Body Confirmation Letter
Certification No: 7425GB454240513

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

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], 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.

Henry Schein Inc.
135 Duryea Road
NY 11747 Melville
United States of America
SRN[2]: US-MF-000021683

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a 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 20 March 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:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 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 devices, 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)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

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
Non-active non-implantable instruments	Class I devices that qualify as re-usable surgical instruments	N/A	N/A
Non-active non-implantable devices for wound and skin care	Class I devices placed on the market in sterile condition	N/A	Certificate 7425GB415200327 NB 0482
Dental procedure devices - various	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Saliva aspirators and saliva absorbents	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Dental instruments, single-use - other	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Non-woven gauzes in pieces	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Dental polishing cups, single-use	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Dental restoration devices	Class IIa	N/A	Certificate 7425GB414210525A NB 0482
Cryotherapy and thermotherapy devices	Class IIa	N/A	Certificate 7425GB414210525A NB 0482

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
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-02-01	7425GB454240201	Initial issue
2024-05-13	7425GB454240513	Addition of Class I devices that qualify as re-usable surgical instruments to the list