

Nürnberg, März 2026

Übergangsbestimmungen der EU-Medizinprodukteverordnung (MDR) – Weiterhin gültiges Inverkehrbringen von Produkten mit abgelaufenem Zertifikat

Sehr geehrte Damen und Herren,

wie Sie wissen, befindet sich die europäische Medizinproduktebranche derzeit in der Übergangsphase zur vollständigen Anwendung der EU-Medizinprodukteverordnung (EU) 2017/745 (MDR). Die MDR sieht spezifische **Übergangsbestimmungen** vor, die es ermöglichen, bestimmte Produkte weiterhin in Verkehr zu bringen, auch wenn die entsprechenden Zertifikate nach der Richtlinie 93/42/EWG (MDD) bereits abgelaufen sind.

Gemäß den geltenden Übergangsregelungen dürfen Produkte mit einem abgelaufenen Zertifikat weiterhin auf dem Markt bereitgestellt werden, **sofern eine gültige, schriftliche Vereinbarung mit der zuständigen Benannten Stelle vor dem Ablauf der ursprünglichen Zertifizierung abgeschlossen wurde**. Diese schriftliche Übereinkunft bestätigt, dass das Produkt sich im MDR-Konformitätsbewertungsverfahren befindet und alle Voraussetzungen der Übergangsbestimmungen erfüllt werden.

Wir möchten Ihnen hiermit bestätigen, dass diese Voraussetzungen für die betroffenen Produkte unseres Hauses erfüllt sind. Damit ist das weitere Inverkehrbringen rechtlich zulässig und vollständig MDR-konform.

Im Anschluss an dieses Schreiben finden Sie folgende Dokumente:

1. **Schriftliche Vereinbarung mit der Benannten Stelle**
2. **Das abgelaufene Zertifikat / die abgelaufene Konformitätserklärung**

Diese Unterlagen dienen Ihrer Transparenz, Dokumentation und Nachweisführung gegenüber Behörden oder internen Qualitätssystemen.

Für Rückfragen stehen wir Ihnen selbstverständlich jederzeit gerne unter medizinprodukte@danone.com zur Verfügung.

Mit freundlichen Grüßen,

Danone Deutschland GmbH

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

SRN: NL-MF-000012729

Your ref.

Our ref. MED/2024-154
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E-mail medical.nl@dekra.com

Arnhem, May 16, 2024

Subject: Notified Body Confirmation Letter

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, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 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:

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

SRN: NL-MF-000012729

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 the Notified Body,

A handwritten signature in blue ink, appearing to read "A.J. Knipmeijer".

A.J. Knipmeijer
Project Manager



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
Flocare Infinity enteral feeding pumps <ul style="list-style-type: none"> - Flocare Infinity + - FLocare Infinity II - Flocare Infinity France - Flocare Infinity III 	Class IIa	Flocare Infinity III will replace the Flocare Infinity +, Flocare Infinity II and Flocare Infinity France	Certificate #93928CE01; NB0344
Flocare Infinity enteral feeding pumps accessories <ul style="list-style-type: none"> - Flocare Infinity Nurse Call - Flocare Infinity Data Cable 	Class IIa	N/A	Certificate #93928CE01; NB0344

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:

N/A

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023/05/31	93928CN46.1	Initial issue (for certificate 93928CE02), covered under agreement 23-140
2024/05/16	93928CN52.1	Revised issue (for certificate 93928CE01), covered under agreement 24-153

DECLARATION OF CONFORMITY (Medical Devices)

DoC NMD 93928CE01_003 INFINITY III pump

Nutricia Medical Devices B.V., having its registered office at *Taurusavenue 167 / 2132 LS Hoofddorp (The Netherlands)*, hereinafter referred to as: “Nutricia”, hereby declares that the distributed CE marked products, specified in the annexed product list, are covered by the CE marking of conformity certificate, reference number: 93928CE01, issued for the first time on July 01, 1999 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and fulfils the relevant provisions of the “Besluit Medische Hulpmiddelen”, the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices, including all subsequent amendments.

Nutricia has implemented a quality assurance system for design, manufacture and final inspection in accordance to the provisions of Annex II of Council Directive 93/42/EC of June 14, 1993 and is subject to periodical surveillance.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the “Besluit Medische Hulpmiddelen”, which is the Dutch transposition of the Council Directive 93/42/EEC” of June 14, 1993, concerning medical devices, which apply to them.

Nutricia ensures and declares that the distributed CE marked products as mentioned, are in compliance with the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of hazardous substances in electrical and electronic equipment (also known as RoHS recast or ROHSII).

This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485:2016, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, and delivered by DEKRA Certification B.V., Arnhem, The Netherlands.

This Declaration of Conformity covers the Flocare® products as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following production site:

- ZEVEX (also trading as MOOG or MMDG-Moog Medical Devices Group) International INC. 4314 ZEVEX Park Lane, Salt Lake City, UT 84123, USA

Hoofddorp, 11 July 2019

RA Manager Medical Devices

Mr. M.E. Lombaerts

Annexes

- Annex A Product list
- Annex B History sheet

Annex A to the Declaration of Conformity (Product list)

**(Flocare® Enteral Feeding Pumps and Nurse Call Interfaces, class IIa)
(GMDN-code 13209 / Enteral feeding pump)**

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE01_003 INFINITY III pump* and specifies the CE-marked products concerned that Nutricia Medical Devices B.V. intends to distribute in conformity with the provisions of the “Besluit medische hulpmiddelen”, which is the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. The following list identifies the product ranges by name, first and last (where applicable) produced Serial Number (SN).

Product name	Product Type	Product Code (REF)	First Product SN	Last Product SN	Production site
FLOCARE® INFINITY™ III	Enteral feeding pump	621825 (SAP 121825)	20190421 1002 *	-	Zevex/Moog USA

SN build up explanation 201904211002 – YYYY DDD X Y ZZZ

YYYY year

DDD day of the year

X Production location (1=MOOG USA / 2=MOOG Lithuania)

Y Version number

ZZZ Sequential numbering

Annex B to the Declaration of Conformity (History sheet)

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE01_003 INFINITY III pump* and specifies the revision history of the Declaration of Conformity, including revisions of the respective Quality System and CE certificates.

EN ISO 13485:2003, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, revised on 15 December 2011 (multi-site structure), re-issued as EN ISO 13485:2012 on 1 September 2013, re-issued on September 30, 2016. *Revised on 2 July 2019 for ISO13485:2016 transition with the new Hoofddorp address.*

CE marking of conformity certificate, reference number 93928CE01, issued for the first time on July 01, 1999, re-issued on June 12, 2008, re-issued on September 1, 2010, re-issued on 1 September 2013, revised as certificate number 93928CE01 on 23 March 2016, re-issued on September 18, 2017. *Revised on 2 July 2019 for the new Hoofddorp address.*

*Rev. 003 Update to new office address from Schiphol to Hoofddorp
Update to ISO13485:2016 and revised CE certificates (new address)*

Rev. 002 Correction SKU number to 621825

Rev. 001 First issuance for new pump Infinity III SKU630599 (ICC2014-020 FDS - Next Generation Pump)