

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.

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Fax +31 88 96 83 100
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_043 Flocare Infinity II pumps and accessories

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, 18 June 2021

RA Manager Medical Devices

Mr. M.E. Lombaerts

Annexes

- Annex A Product list
- Annex B History sheet
- Annex C Discontinued product list

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_043 Flocare Infinity II pumps and accessories* 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 products by name and article-number.

Product name	Product Type	Product Code (REF)	SAP (logistical) code	First Product SN	SN Range	Production site
FLOCARE® INFINITY (II)						
(Internal Nomenclature “Infinity II” or ‘Infinity’)	Flocare® Infinity™ enteral feeding pump W-EUROPE	35676	40405	76650001 (year 2006)	76x 00001 till 76x 74999 (where x can be 6, 7, 8, 9, 0, 1, 2, 3, 4, representing years 2006 - 2014) 76y 75001 till 76y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
	Flocare® Infinity™ enteral feeding pump UK EXPORT	35679	40407	79650001 (year 2006)	79x 00001 till 79x 74999 (where x can be 6, 7, 8, 9, 0, 1, 2, 3, 4, representing years 2006 - 2014) 79y 75001 till 79y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
	Flocare® Infinity™ enteral feeding pump N-EUROPE	35682	40409	82650001 (year 2006)	82x 00001 till 82x 74999 (where x can be 6, 7, 8, 9, 0, 1, 2, 3, 4, representing years 2006 - 2014) 82y 75001 till 82y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
FLOCARE® INFINITY FRANCE						
(Internal Nomenclature “Infinity II France” or ‘Infinity France’)	Flocare® Infinity™ enteral feeding pump FRANCE	35685	40461	85650001 (year 2006)	85x 00001 till 85x 74999 (where x can be 6, 7, 8, 9, 0, 1, 2, 3, 4, representing years 2006 - 2014) 85y 75001 till 85y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
FLOCARE® INFINITY +						
(Internal Nomenclature “Infinity II +” or ‘Infinity +’)	Flocare® Infinity™ + enteral feeding pump W-EUROPE	35677	40406	77750001 (year 2007)	77x 00001 till 77x 74999 (where x can be 7, 8, 9, 0, 1, 2, 3, 4, representing years 2007 - 2014) 77y 75001 till 77y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc

Product name	Product Type	Product Code (REF)	SAP (logistical) code	First Product SN	SN Range	Production site
(Internal Nomenclature "Infinity II +" or 'Infinity +')	Flocare® Infinity™ + enteral feeding pump UK EXPORT	35680	40408	80750001 (year 2007)	80x 00001 till 80x 74999 (where x can be 7, 8, 9, 0, 1, 2, 3, 4, representing years 2007 - 2014) 80y 75001 till 80y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
	Flocare® Infinity™ + enteral feeding pump N-EUROPE	35683	40435	83750001 (year 2007)	83x 00001 till 83x 74999 (where x can be 7, 8, 9, 0, 1, 2, 3, 4, representing years 2007 - 2014) 83y 75001 till 83y 99999 (where y can be 5, 6, 7, 8, 9, 0, 1, 2, 3, 4; representing years 2015 -2024)	Zevex, Inc
PUMP ACCESSORIES						
FLOCARE® INFINITY Nurse Call	Nurse call interface for Flocare Infinity™	35752	40345	03081	n/a	Zevex, Inc
FLOCARE® INFINITY Data Cable	Data cable for Flocare Infinity™	35776	40336	08051	n/a	Zevex, Inc

Annex B to the Declaration of Conformity (History sheet)

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

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE01_043 Flocare Infinity II pumps and accessories* 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 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, *re-issued on 25 May 2021*.

- Rev. 043 *New CE certificate issuance date*
- Rev. 042 Inclusion SAP logistical codes
- Rev. 041 Update to new office address from Schiphol to Hoofddorp
Update to ISO13485:2016 and revised CE certificates (new address)
- Rev. 040 Alignment supplier name to ZEVEX, Inc
- Rev. 039 Update new CE certificate re-issued 18 September 2017
- Rev. 038 Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.
- Rev. 037 Transfer to Annex II certification (ICC2016-009)
- Rev. 036 Correction of last F800 FI pump SN
Inclusion of first and last production SN data for F800 pump produced at Nutricia (ie before MOOG)
New DoC layout including discontinued product list
- Rev. 035 Correction of last F800 CZ and GR pump SN
- Rev. 034 Addition of Annex C discontinued products list (included F800 & Infinity I)
Addition of Infinity SN range
- Rev. 033 Addition last serial number production of the F800 pumps produced at MOOG (F800 delisting ICC2012-007)
- Rev. 032 Removal of Flocare Infinity I and pediatric pumps of which last produced SN has been included in previous DoC.
Addition of Declaration of Conformity to recast ROHS Directive 2011/65/EC.
- Rev. 031 Update DoC due to recertification 1 September 2013 (EN ISO 13485:2012).
- Rev. 030 Included first batch information F800 pumps and last batch information Infinity I pumps.
- Rev. 029 Correction KEMA to DEKRA and included reference to multi-site QMS
Removal feeding pumps as produced by NMD BV (all pumps are manufactured by Zevex/MOOG) & removed production side NMD as NMD does not produce any pumps since several years.
Updated lay-out product list.
- Rev. 028 Alignment Product name with product labeling: Flocare infinity enteral feeding pump to Flocare Infinity
- Rev. 027 Addition of GMDN-code
Eliminated various REF CC related to the Flocare® MicroMAX enteral feeding pump that have been provided with the last batch numbers in the previous Declaration of Conformity
Eliminated REF CC 35722 related to the Flocare® Nurse call interface and CC 35755 related to the Flocare® Infinity charger that have been provided with the last batch numbers in the previous Declaration of Conformity
Addition of last product LOTs the Flocare 800 enteral feeding pump produced by NMD BV
Addition of the Flocare 800 enteral feeding pump (with first batch numbers) produced by Zevex/Moog
- Rev. 026 Addition of new re-issue date September 1st 2010
Eliminated: “, amended by 2007/47 EC of 5 September 2007”

Annex C to the Declaration of Conformity (Discontinued Product list)

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

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE01_043 Flocare Infinity II pumps and accessories* and specifies the discontinued products within the identified certificate. Product ranges are identified by first and last produced Serial Number (SN). After the designed technical life time of 5 years after the last produced SN, the SKU will be removed from the DoC in full.

Product name	Product Type	Product Code (REF)	First Product SN	Last Product SN*	Production site
Flocare 800 enteral feeding pump	Flocare 800, Netherlands	35647	47750001	471250016	Zevex/Moog
	Flocare 800, France	35648	48850001	481350016	Zevex/Moog
	Flocare 800, United Kingdom	35649	49750001	49050002	Zevex/Moog
	Flocare 800, Brazil 110 V	35650	50050001	501150350	Zevex/Moog
	Flocare 800, Brazil 220 V	35651	51050001	511150150	Zevex/Moog
	Flocare 800, Denmark	35653	n/a	n/a	Zevex/Moog
	Flocare 800, Denmark, screened power cable red	35654	n/a	n/a	Zevex/Moog
	Flocare 800, Australia	35655	55050001	551150004	Zevex/Moog
	Flocare 800, Ireland	35656	n/a	n/a	Zevex/Moog
	Flocare 800, Czech Republic	35657	57750001	571250002	Zevex/Moog
	Flocare 800, Slovakia	35658	n/a	n/a	Zevex/Moog
	Flocare 800, Poland	35659	59850001	591350100	Zevex/Moog
	Flocare 800, Hungary	35660	60850001	601250002	Zevex/Moog
	Flocare 800, Turkey	35661	61750001	611350301	Zevex/Moog
	Flocare 800, Belgium	35662	n/a	n/a	Zevex/Moog
	Flocare 800, Greece	35664	64850001	64950004	Zevex/Moog
	Flocare 800, Finland	35665	n/a	n/a	Zevex/Moog
	Flocare 800, Italy	35666	66850001	661350030	Zevex/Moog
	Flocare 800, South Africa	35668	n/a	n/a	Zevex/Moog
	Flocare 800, China	35667	67750001	671150390	Zevex/Moog
	Flocare 800, Qatar	35669	n/a	n/a	Zevex/Moog

	Flocare 800, Dubai	35671	n/a	n/a	Zevex/Moog
	Flocare 800, Portugal	35672	72750001	72050020	Zevex/Moog
	Flocare 800, Norway	35673	n/a	n/a	Zevex/Moog
	Flocare 800, Germany	35674	n/a	n/a	Zevex/Moog
	Flocare 800, Netherlands	35647	9900131		NMD
	Flocare 800, France	35648	9900741		NMD
	Flocare 800, United Kingdom	35649	9900031		NMD
	Flocare 800, Brazil 110 V	35650	89011620		NMD
	Flocare 800, Brazil 220 V	35651	9903206		NMD
	Flocare 800, Denmark	35653	9900813		NMD
	Flocare 800, Denmark, screened power cable red	35654	20000326		NMD
	Flocare 800, Australia	35655	9900081		NMD
	Flocare 800, Ireland	35656	9900181		NMD
	Flocare 800, Czech Republic	35657	9903036		NMD
	Flocare 800, Slovakia	35658	9900953		NMD
	Flocare 800, Poland	35659	9900461		NMD
	Flocare 800, Hungary	35660	88013508		NMD
	Flocare 800, Turkey	35661	9900511		NMD
	Flocare 800, Belgium	35662	9900341		NMD
	Flocare 800, Greece	35664	9900001		NMD
	Flocare 800, Finland	35665	9903116		NMD
	Flocare 800, Italy	35666	9901088		NMD
	Flocare 800, South Africa	35668	9902179		NMD
	Flocare 800, China	35667	9702690		NMD
	Flocare 800, Qatar	35669	005769		NMD
	Flocare 800, Dubai	35671	88020720		NMD
	Flocare 800, Portugal	35672	9900111		NMD
	Flocare 800, Norway	35673	9901308		NMD

	Flocare 800, Germany	35674	88023291		NMD
Flocare® Infinity (I)	Flocare® Infinity™ enteral feeding pump W-EUROPE	35676	204337001	205019015	Zevex/Moog
			76500011	76610096	Zevex/Moog
	Flocare® Infinity™ + enteral feeding pump W-EUROPE	35677	104197001	104205002	Zevex/Moog
			304343001	305021002	Zevex/Moog
	Flocare® Infinity™ enteral feeding pump UK EXPORT	35679	10418305	104183107	Zevex/Moog
			204341002	205024027	Zevex/Moog
			7950003	79604551	Zevex/Moog
	Flocare® Infinity™ enteral feeding pump N-EUROPE	35682	82500002	82602706	Zevex/Moog
Flocare® Infinity paediatric	Flocare® Infinity™ Paediatric enteral feeding pump W-EUROPE	35678	10414802	104205001	Zevex/Moog
			404337003	405020001	Zevex/Moog
	Flocare® Infinity™ Paediatric enteral feeding pump UK EXPORT	35681	104197056	104197105	Zevex/Moog
			404337001	405021001	Zevex/Moog

*explanation on F800 pump SN produced at Zevex

ZZYXXXXX	Serial number buildup until 2010 ZZ = country code, Y= date of manufacturing (2010 = 0), XXXXX = 50001 is the initial F800 V2 serial number
ZZYYXXXXX	Serial number buildup from 2011 onwards ZZ = country code, YY= date of manufacturing (2011 = 11), XXXXX = 50001 is the initial F800 V2 serial number