

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
Tel. +31 88 96 83 009
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

EC CERTIFICATE

Number: 93928CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Nutricia Medical Devices B.V.

Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

For the product category(ies)

Flocare® Infinity™ Enteral feeding pumps and accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

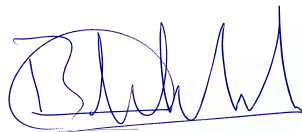
Documents, that form the basis of this certificate:

Certification Notice 93928CN, initially dated 1 July 1999
Addendum, initially dated 2 December 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 1 July 1999
Reissued: 25 May 2021
Revised: 2 July 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 93928CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Flocare® Infinity™ Enteral feeding pumps and accessories

Issued to:

Nutricia Medical Devices B.V.

**Taurusavenue 167
2132 LS Hoofddorp
The Netherlands**

This certificate covers the following product(s):

Flocare® Infinity™ Enteral feeding pumps accessories:

- Flocare® Infinity™ Nurse Call
- Flocare® Infinity™ Data Cable

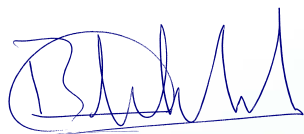
Flocare® Infinity™ enteral feeding pumps

- Flocare® Infinity™ +
- Flocare® Infinity™ II
- Flocare® Infinity™ France
- Flocare® Infinity™ III

Initial date: 2 December 2002

Revision date: 2 July 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396