CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE

Règlement (UE) 2017/745, Annexe IX Chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745, Annex IX Chapters I and III

Certificat/*Certificate:* N° 39124 rev. 3

Délivré le/*Issued on:* November 20th, 2023

Certificat délivré à/*Certificate issued to:* **UNOMEDICAL A/S**

Aaholmvej 1-3, Osted

4320 LEJRE DENMARK

SRN: DK-MF-000002447

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602644_P4 / P602289 / P607545, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced P602644_P4 / P602289 / P607545, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Infusion sets (rigid and soft cannula, angled and straight insertion) for subcutaneous therapy applications.

Sets de perfusion (canule rigide ou souple, pour insertion en biais ou droite) pour applications thérapeutiques sous cutanées.

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité */Effective date:* November 20th, 2023 (included)

Valable jusqu'au */Expiry date:* August 30th, 2027 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

On behalf of the President
Béatrice LYS
Technical Director

GMED - 39124 rev. 3
Modifie le certificat 39124-2

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:* **Non applicable /** *Not applicable*

2. **Identification des sites /** *Identification of sites:*

Unomedical a/s - Aaholmvej 1-3, Osted - 4320 Lejre – Denmark
Unomedical Devices S.A De C.V. - Avenida Fomento Industrial, Lote 9, M3 – Parque Industrial del Norte Reynosa, Tamaulipas, Mexico C.P. 88736
Unomedical Devices S.A. De C.V. - Avenida Industrial Falcon, Seccion 4, Lote 7 – Parque Industrial del Norte Reynosa, Tamaulipas, Mexico C.P. 88736

3. **Identification des dispositifs /** *Identification of devices:*

<table>
<tr><th>Nom du dispositif médical
Medical device name</th><th>Nom commercial
Commercial name</th><th>Destination (DM classe IIb uniquement)
Intended use (MD Class IIb only)</th><th>Classe du DM
MD Class</th><th>Référence au certificat requis pour la mise sur le marché (uniquement DM classe III et IIb)
Reference to the certificate required for placing on the market
(only DM class III and IIb implantable)</th></tr>
<tr><td>Neria™ Guard</td><td>
<table>
<tr><th>Commercial name</th><th colspan="4">Technical product description</th><th>Item#</th></tr>
<tr><th></th><th>Connector</th><th>Cannula</th><th>Tubing</th><th>Packaging</th><th></th></tr>
<tr><td>Neria™ Guard</td><td>Luer lock</td><td>6 mm</td><td>12 cm</td><td>10-pack</td><td>704012-5226</td></tr>
<tr><td>Neria™ Guard</td><td>Luer lock</td><td>6 mm</td><td>30 cm</td><td>10-pack</td><td>704030-5226</td></tr>
<tr><td>Neria™ Guard</td><td>Luer lock</td><td>6 mm</td><td>60 cm</td><td>10-pack</td><td>704060-5226</td></tr>
<tr><td>Neria™ Guard</td><td>Luer lock</td><td>6 mm</td><td>80 cm</td><td>10-pack</td><td>704080-5226</td></tr>
<tr><td>Neria™ Guard</td><td>Luer lock</td><td>6 mm</td><td>110 cm</td><td>10-pack</td><td>704110-5226</td></tr>
</table>
</td><td>Le produit est destiné à la perfusion par voie sous-cutanée d'immunoglobulines pour le traitement du déficit immunitaire primaire, apomorphine et de foscarbidopa/foslévodopa pour la maladie de Parkinson et morphine (hydromorphone, sulfate de morphine et chlorure de morphine) pour la prise en charge de la douleur, de sérum physiologique pour la</td><td>IIb non implantable</td><td>Non applicable / Not applicable</td></tr>
</table>

On behalf of the President
Béatrice LYS
Technical Director

	Neria™ Guard	Luer lock	9 mm	12 cm	10-pack	704012-5229	déshydratation et de mésylate de déféroxamine pour la thalassémie. *The product is intended for the subcutaneous infusion of immunoglobulins for the treatment of primary immune deficiency, apomorphine and foslevodopa/ foscarbidopa for parkinson's disease, morphine (hydromorphone, morphine sulfate and morphine chloride) for pain management therapy, saline for dehydration and deferoxamine mesylate for thalassemia.*		
	Neria™ Guard	Luer lock	9 mm	30 cm	10-pack	704030-5229			
	Neria™ Guard	Luer lock	9 mm	60 cm	10-pack	704060-5229			
	Neria™ Guard	Luer lock	9 mm	80 cm	10-pack	704080-5229			
	Neria™ Guard	Luer lock	9 mm	110 cm	10-pack	704110-5229			

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the preceeding certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39124 rev. 0	**31/08/2022** *08/31/2022*	**Correction du point 5 pour ajouter les informations spécifiques relatives aux limitations de la validité du certificat conformément au courrier de notification CLE/AVA/1641/22** *Correction of part 5 to add specific information relating to the limitations to the validity of the certificate as per notification letter CLE/AVA/1641/22*
39124 rev. 1	**24/10/2022** *10/24/2022*	**Mise à jour de la destination du produit** *Update of the intended use of the product*
39124 rev. 2	**02/12/2022** *12/02/2022*	**Nouvelle référence de rapport dans le cadre du maintien de la certification** *New file reference in the framework of the maintenance of the certification*

On behalf of the President
Béatrice LYS
Technical Director

5. **Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat /** *If applicable, specific information relating to the limitations to the validity of the certificate :*

   Seule la stérilisation selon le cycle #78 avec utilisation de la chambre d'aération NK4 est approuvée. La double stérilisation n'est pas approuvée. / *Only single sterilization cycle#78 with the use of NK4 heated aeration is approved. Double sterilization is not approved.*

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat /** *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate :* **Non applicable** / *Not applicable*

On behalf of the President
Béatrice LYS
Technical Director

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CERTIFICATE OF CONFORMITY

Manufacturer: Unomedical A/S
Aaholmvej 1-3, Osted
4320 Lejre, Denmark

Date: 04.OKT.2024

This is to certify that the following products supplied to :

Customer: ConvaTec Ltd
Prod. Descr.: Neria Guard Grey 80/9

Have been developed, manufactured, sterilized and inspected in accordance with the requirements of:

21 CFR Part 820:	Quality system regulation.
ISO 13485:2016:	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 11135:2014:	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
DS/EN 556-1:2001:	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilised medical devices.
Regulation (EU) 2017/745:	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

The products are furthermore non-pyrogenic according to currently valid USP requirements and the ethylene oxide residuals are below the maximum allowable values stated in ISO 10993-7.

Approved by:

Pia Jensen

Quality Control Department

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CERTIFICATE OF CONFORMITY

Manufacturer: Unomedical A/S
Aaholmvej 1-3, Osted
4320 Lejre, Denmark

Date: **04.OKT.2024**

This is to certify that the following products supplied to :

Customer: **ConvaTec Ltd**
Prod. Descr.: **Neria Guard Grey 110/6**

Have been developed, manufactured, sterilized and inspected in accordance with the requirements of:

21 CFR Part 820:	Quality system regulation.
ISO 13485:2016:	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 11135:2014:	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
DS/EN 556-1:2001:	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilised medical devices.
Regulation (EU) 2017/745:	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

The products are furthermore non-pyrogenic according to currently valid USP requirements and the ethylene oxide residuals are below the maximum allowable values stated in ISO 10993-7.

Approved by:

Pia Jensen

Quality Control Department