Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 18 04 33038 028

Digitally signed by Bunic Gheorghe
Date: 2020.04.19 19:47:21 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer:

Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick
IRELAND

Facility(ies):

Cook Ireland Limited
O'Halloran Road, National Technology Park, Limerick, IRELAND

Product Category(ies):

Disposable devices and accessories for use in vascular, urological, gastroenterological pulmonary procedures (class IIa and IIb) including catheters, introducers, wires and drainage sets, electrosurgical and non-active instruments, stents and stent grafts, needles and cannulae. Vascular stents and delivery systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75942541

Valid from: 2018-06-19
Valid until: 2023-06-18

Date, 2018-06-13

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* / CERTIFICADO **n° 31390 rev. 13**
Délivrée à Paris le 20 novembre 2019
Issued in Paris on November 20th, 2019
Establecido en Paris, el 20 noviembre 2019

ATTESTATION CE / *EC CERTIFICATE* / CERTIFICADO CE

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
Aprobación del sistema completo de Seguro de la calidad
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
ANEXO II excluyendo el punto 4 Directiva 93/42/CEE relativa a los productos sanitarios
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer* / Fabricante

LABORATOIRES ANIOS
1 rue de l'Espoir
59260 LEZENNES FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category* / Categoría del producto

Détergents désinfectants ou désinfectants pour DM invasifs et/ou non invasifs

Detergent disinfectant or disinfectant for invasive and/or non invasive devices

Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P177315, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P177315, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

GMED certifica que después del examen de los resultados indicados en el expediente P177315, el sistema de calidad para el diseño, la fabricación y el control final - de los productos sanitarios enunciados anteriormente - cumple con los requisitos del anexo II excluyendo el punto 4 de la Directiva 93/42/CEE.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date* / Fecha efectiva : **November 20th, 2019 (included)**

Valable jusqu'au / *Expiry date* / Fecha de expiración :**June 10th, 2021 (included)**

GMED SAS GMED SAS
GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3_ESP-F-V0-07-2018

GMED - 31390 rev. 13
Modifie le certificat 31390-12

Catégorie du (des) dispositifs / *Device(s) category* / Categoría del producto :

Version française :
Détergents désinfectants ou désinfectants pour DM invasifs et/ou non invasifs :
- **Désinfectants Circuits dialyse**
- **Désinfectants manuels et/ou machines pour DM invasifs**
- **Détergents Désinfectants manuels et/ou machines pour DM invasifs**
- **Détergents Désinfectants manuels et/ou machines pour DM non invasifs**
- **Sprays détergents désinfectants ou désinfectants pour DM invasifs**
- **Sprays détergents désinfectants ou désinfectants pour DM non invasifs**
- **Lingettes détergentes désinfectantes ou désinfectantes pour DM invasifs**
- **Lingettes détergentes désinfectantes ou désinfectantes pour DM non invasifs**

Version anglaise :
Detergents disinfectants or disinfectants for invasive and/or non-invasive devices :
- *Disinfectants for dialysis circuits*
- *Disinfectants for manual use and/or automatic machines for invasive devices*
- *Detergent disinfectant for manual use and/or automatic machines for invasive devices*
- *Detergent disinfectant for manual use and/or automatic machines for non-invasive devices*
- *Detergent disinfectant or disinfectant sprays for invasive devices*
- *Detergent disinfectant or disinfectant sprays for non-invasive devices*
- *Detergent disinfectant or disinfectant wipes for invasive devices*
- *Detergent disinfectant or disinfectant wipes for non-invasive devices*

Version espagnole:
Detergentes desinfectantes o desinfectantes para DM invasivos y/o no invasivos :
- Desinfectantes para circuitos diálisis,
- Desinfectantes manuales y/o máquinas para DM invasivos,
- Detergentes desinfectantes manuales y/o máquinas para DM invasivos
- Detergentes desinfectantes manuales y/o máquinas para DM no invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM invasivos
- Pulverizadores detergentes desinfectantes o desinfectantes para DM no invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM invasivos
- Toallitas detergentes desinfectantes o desinfectantes para DM no invasivos

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106138

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb
Double J stent & set

Class IIa
PCN catheter & set
Ureteral catheter
Malecot catheter
Re-entry malecot catheter
Suprapubic catheter
Braided shaft catheter
Dual lumen catheter
Facial dilator
Amplatz dilator & set
Ureteral dilator & set
Ureteral balloon dilator
Double J stent & set
Mono J stent
Endopyelotomy stent
Guidewire
IP Needle
Chiba needle
Stone basket
Perk basket

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND20190101

Valid from: 2019-10-22
Valid until: 2024-10-21

Date, [#ISU_DT#]

Stefan Preiß
Head of Certification/Notified Body

Draft From CBW 2.0 - Production System (Build - 20190829.1)

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106138

Facility(ies):

Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class Is
Urine bag connector
Penile clamp
Evacuator
IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: IND20190101

Valid from: 2019-10-22
Valid until: 2024-10-21

Date, [#ISU_DT#]

Stefan Preiß
Head of Certification/Notified Body

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138

Facility(ies):

Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106138

Holder of Certificate: **Marflow AG**
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Facility(ies): Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:

Scope of Certificate: **The Design, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND20190101

Valid from: 2019-10-22
Valid until: 2022-10-21

Date, [#ISU_DT#]

Stefan Preiß
Head of Certification/Notified Body

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