ANGIMED
www.angimed.it
tel.085.975035 fax 085.9960203
info@angimed.it

Digitally signed by Bunic Gheorghe
Date: 2019.12.01 19:27:55 EET
Reason: MoldSign Signature
Location: Moldova

REV. 14.01.2019

DECLARATION OF CONFORMITY CE APPLICATIONS WITH DIRECTIVES 93/42 / EEC OF 14 JUNE 1993 - 2007/47 / EC OF SEPT EMBER 5, 2007

Alessandro Di Teodoro, as the legal representative of Angimed S.r.l. ,

declare

that medical devices class I below identified, meet the Essential Requirements of the Directive 93/42/EC of 14 June 1993 and 2007/47/EC of September 5, 2007 and are used for their intended use. This statement is based on the technical documentation referenced in the Procedure of Conformity Annex VII .

ANGIMED SRL - MANUFACTURING PLANT:

Corso Umberto I, 590 / ED.66 - 65015 Montesilvano (PE) Italy

CODE	PRODUCT DESCRIPTION
AM001N	BEDPAN COVER
AM001	BEDPAN COVER
AM002	P.P. -URINE SYSTEM
AM002HM	P.P. -URINE SYSTEM WHIT LANYARD
AM003	RIG -VOMIT SYSTEM
AM003HM	RIG -VOMIT SYSTEM WHITH LANYARD
AM004	SGAIEL- POWDER SUPER ABSORBENT 400GR.
AM005	SGAIEL- POWDER SUPER ABSORBENT 200GR.
AM006	SGAIEL- POWDER SUPER ABSORBENT 1000GR.
AM007	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 05 GR.
AM008	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 10 GR.
AM009	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 15 GR.
AM013	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 13 GR.
AM020	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 20 GR.
AM025	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 25 GR.
AM050	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 50 GR.

Alessandro Di Teodoro
(C.E.O.)

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. DM/18/182/S

CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

IT IS HEREBY CERTIFIED THAT THE QUALITY MANAGEMENT SYSTEM OF

ANGIMED S.R.L.

Viale Nettuno 25 66023 FRANCAVILLA AL MARE (CH) ITALIA

Per informazioni sulla validità del certificato, visitare il sito www.rina.org

For information concerning validity of the certificate, you can visit the site www.rina.org

NELLE SEGUENTI UNITÀ OPERATIVE */ IN THE FOLLOWING OPERATIONAL UNITS*

CORSO UMBERTO I, 590 65015 Montesilvano (PE) ITALIA

È CONFORME ALLA NORMA

IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2016

PER I SEGUENTI CAMPI DI ATTIVITÀ / *FOR THE FOLLOWING FIELD(S) OF ACTIVITIES*

PROGETTAZIONE E PRODUZIONE DI DISPOSITIVI MEDICI NON ATTIVI MONOUSO PER LO SMALTIMENTO DI FLUIDI CORPOREI NATURALMENTE ESCRETI

DESIGN AND PRODUCTION OF NON-ACTIVE MEDICAL DEVICES FOR THE DISPOSAL OF NATURALLY EXCRETE BODY FLUIDS

La validità del presente certificato è subordinata a sorveglianza periodica annuale / semestrale ed al riesame completo del sistema di gestione con periodicità triennale

The validity of this certificate is dependent on an annual / six monthly audit and on a complete review, every three years, of the management system

Riferirsi al Manuale della Qualità per i dettagli delle esclusioni ai requisiti della norma

Reference is to be made to the Quality Manual for details regarding the exemptions from the requirements of the standard

L'uso e la validità del presente certificato sono soggetti al rispetto del documento RINA: Regolamento per la Certificazione di Sistemi di Gestione per la Qualità

The use and validity of this certificate are subject to compliance with the RINA document : Rules for the certification of Quality Management Systems

Prima emissione
First Issue 21.12.2018

Data scadenza
Expiry Date 20.12.2021

Data revisione
Revision date 21.12.2018

Simone Farinelli

Pescara Management System Certification, Head

RINA Services S.p.A.
Via Corsica 12 - 16128 Genova Italy

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 002 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale
CISQ is the Italian Federation of management system Certification Bodies

Form CERSISGE-01/2018

CISQ is a member of

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THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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CERTIFICATO N. 37542/18/S
CERTIFICATE No.

Per informazioni sulla validità del certificato, visitare il sito www.rina.org

For information concerning validity of the certificate, you can visit the site www.rina.org

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
IT IS HEREBY CERTIFIED THAT THE QUALITY MANAGEMENT SYSTEM OF

ANGIMED S.R.L.

Viale Nettuno 25 66023 FRANCAVILLA AL MARE (CH) ITALIA

NELLE SEGUENTI UNITÀ OPERATIVE */ IN THE FOLLOWING OPERATIONAL UNITS*

CORSO UMBERTO I, 590 65015 Montesilvano (PE) ITALIA

Per i requisiti della norma non applicabili al campo di applicazione del sistema di gestione dell'organizzazione, riferirsi alle informazioni documentate relative.

Reference is to be made to the relevant documented information for the requirements of the standard that cannot be applied to the Organization's management system scope

È CONFORME ALLA NORMA */ IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER I SEGUENTI CAMPI DI ATTIVITÀ / *FOR THE FOLLOWING FIELD(S) OF ACTIVITIES*

IAF:12

PROGETTAZIONE E PRODUZIONE DI DISPOSITIVI MEDICI, NON ATTIVI, PER LO SMALTIMENTO DI FLUIDI CORPOREI NATURALMENTE ESCRETI.

DESIGN AND PRODUCTION OF NON-ACTIVE MEDICAL DEVICES FOR THE DISPOSAL OF NATURALLY EXCRETE BODY FLUIDS.

La validità del presente certificato è subordinata a sorveglianza periodica annuale / semestrale ed al riesame completo del sistema di gestione con periodicità triennale
The validity of this certificate is dependent on an annual / six monthly audit and on a complete review, every three years, of the management system
L'uso e la validità del presente certificato sono soggetti al rispetto del documento RINA: Regolamento per la Certificazione di Sistemi di Gestione per la Qualità
The use and validity of this certificate are subject to compliance with the RINA document : Rules for the certification of Quality Management Systems

Prima emissione
First Issue 20.12.2018

Data scadenza
Expiry Date 19.12.2021

Data revisione
Revision date 20.12.2018

Simone Farinelli
Pescara Management System Certification, Head

RINA Services S.p.A.
Via Corsica 12 - 16128 Genova Italy

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 002 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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Form CERSISGE-01/2018

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
[illegible]

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170030

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **TURKUAZSAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLERİSAN.VE TİC, LTD. ŞTİ.**
Yakuplu Mah. Birlik Cad No:34/3 Beylikdüzü, İstanbul, Turkey

for design, manufacturing and final inspection of medical device(s)

Catheter gel with lidocain - class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **203303-01 of 30.5.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 05.06.2017 with validity until 04.06.2022.
The validity of this Certificate is limited until: 04.06.2022

05.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

203303-01

Certificate

SERTİFİKA

TÜRCERT Sertifikasyon Merkezi
iş bu belge ile/TÜRCERT Certification Body
with this document.

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TIC. A.Ş.

YAKUPLU MAH. BİRLİK CAD. NO:32/1 BEYLİKDÜZÜ İSTANBUL TÜRKİYE

şirketinin;/ of the company

RÖNTGEN SOLÜSYONLARI, TIBBİ CİHAZ DEZENFEKTANLARI VE MEDİKAL CİHAZLAR İÇİN STERİL BUĞU ÖNLEYİCİ SOLÜSYON, STERİL VE STERİL OLMAYAN KAYGANLAŞTIRICI JELLER, DOĞUM JELLERİ, STERİL VE STERİL OLMAYAN ULTRASON JELLERİ, STERİL VE STERİL OLMAYAN BURUN SOLÜSYONLARI, BİT ŞAMPUANI VE SPREYİ VE SMEAR DOKU SABİTLEYİCİ SPREYİNİN TASARIMI, ÜRETİMİ VE SATIŞI

MANUFACTURING AND SALES OF MEDICAL X-RAY SOLUTIONS, MEDICAL DEVICE DISINFECTANT, STERILE ANTIFOG SOLUTION FOR MEDICAL DEVICES, STERILE AND NON-STERILE LUBRICANT GELS, OBSTETRIC GEL, STERILE & NON-STERILE ULTRASOUND GELS, STERILE & NON-STERILE NASAL SOLUTIONS, ANTI-LICE AND NITS SHAMPOO AND SPRAY AND SMEAR SPRAY

belirlenen standardın uygulanması konusunda tıbbi cihazlar için yönetim sistemi yürürlüğe koyduğunu ve uygulamakta olduğunu taahhüt eder./ Effective medical devices management system and guarenteesthat you put in to apply

2018101013284-01MDMS Sayılı rapordaki inceleme ile/
2018101013284-01MDMSwith the nr. examination report;

TS EN ISO 13485:2016

şartlarının sağlanmış olduğu kanıtlanmıştır, iş bu sertifika yıllık ara denetimlerinin yapılması kaydıyla **08.08.2021** tarihine kadar geçerlidir./ Its proven that requirements are provided. This certificate is valid until **08.08.2021** with the condition of surveillance audits done

Sertifika Kayıt No/ Certificate Registration Nr : 2018101013284-01
Sertifika Yayın Tarihi / Date of Issue : 10.10.2018
Sertifika Geçerlilik Tarihi / Certificate Validity Date : 08.08.2021

TÜRCERT

Türcert A.Ş.
Belgelendirme Bölümü Adına

ÖSAS
ÖSTERREICH
Spezielle Akkreditierung Service
austria
ÖSAS Ö-41

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME ANONİM ŞİRKETİ
Adres : Sanayi Mh. Atatürk Cd. No 57/17 Güngören / İstanbul - Türkiye
Telefon: 0 212 909 35 90 - 0 312 500 00 10 www.turcert.com

bolsaplast

ISO 9001 BUREAU VERITAS Certification

ISO 13485 BUREAU VERITAS Certification

CERTIFICATION
DECLARATION OF CE CONFORMITY – Directive 93/42/CE

BOLSAPLAST S.L., supplies under CE mark, the following products:

- Paper/Film Flat Bags (MBO)
- Paper/Film Selfsealing Bags (MBA)
- Paper/Film Gusset Bags (MBF)
- Paper/Film Flat Reels (MRP)
- Paper/Film Gusset Reels (MRF)
- Tyvek®/Film Flat Bags (MBT)
- Tyvek®/Film Flat Reels (MRT)
- Steam Tape (MCV)
- Bolsacrepe (MCREP)
- Bolsacover (MBCOVER)

All our products are adequate for hospital using, in sterilization processes of medical-surgical products and similar materials.

Products above mentioned are produced in conformity with EN 868-2/3/4/5 and ISO 11607-1, about packaging and systems for medical products to be sterilized.

Our products meet essential requirements in Annex I of the EEC/93/42 Directive and they belong to Class 1 non sterile packaging.

According to our quality system, all necessary processes are took to agree with manufacturing and service parameters established by our quality management system under norm ISO 9001-2008 and ISO13485-2013. Surveillance process and technical information are developed to also agree with norms.

Signature : Jaume Pares Criville
Date : 31st March 2017

bolsaplast
BOLSAPLAST, S.L. - CIF: B-08808990
Domicilio Fiscal: C/ BERNAT METGE, 110-112
Correspondencia: C/ BERNAT METGE, 112
08205 - SABADELL (Barcelona) SPAIN
Tel.: 34 93 711 73 61 - Fax: 34 93 712 23 55

BUREAU VERITAS
Certification

Certificación

Certification

Concedida a / Awarded to

BOLSAPLAST SL

C/ BERNAT METGE,110-112
08205 SABADELL
SPAIN

Bureau Veritas Certification certifica que el Sistema de Gestión ha sido auditado y encontrado conforme con los requisitos de la norma:

Bureau Veritas Certification certifies that the Management System has been audited and found to be in accordance with the requirements of standard:

NORMA / STANDARD

UNE EN ISO 13485:2013

El Sistema de Gestión se aplica a:

Scope of certification

FABRICACIÓN Y COMERCIALIZACIÓN DE EMBALAJE DESTINADO A PRODUCTOS MÉDICOS.

MANUFACTURING AND MARKETING OF PACKAGING FOR MEDICAL PRODUCTS.

Número del certificado *Certificate Number*	**ES077880-1**
Aprobación original : *Original approval date :*	***22/01/2014***
Certificado en vigor: *Effective date:*	***22/01/2017***
Caducidad del certificado: *Certificate expiration date:*	***21/01/2020***

Directora de Certificación / Certification Manager

Este certificado está sujeto a los términos y condiciones generales y particulares de los servicios de certificación
This certificate is valid, subject to the general and specific terms and conditions of certification services

Entidad de Certificación / Certification Body: Bureau Veritas Iberia S.L.
C/ Valportillo Primera 22-24, Edificio Caoba, Pol. Ind. La Granja, 28108 Alcobendas - Madrid, Spain

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
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

Facility(ies):

Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

-/-

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

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

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

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

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