Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° *Certificate no.*	**QPZ-1916-19**	Addendum n° *addendum no.*	//-//	Data prima emissione *First issue date*	**19.09.2019**
				Data di emissione corrente *Current issue date*	**19.09.2019**
				Data di scadenza *Expiry date*	**26.05.2024**

GARANZIA DELLA QUALITA' DELLA PRODUZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

PRODUCTION QUALITY ASSURANCE

according to Annex V of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

L'Istituto Superiore di Sanità, Organismo Notificato 0373, certifica che il sistema di garanzia della qualità della produzione attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the production quality assurance enforced by

M.V. S.r.l.

***Sede Legale/** Registered Office:*
Via F.lli Cervi, 7 – 46023 Gonzaga loc. Palidano (MN) ITALIA

Altre sedi del Fabbricante /Other sites of the Manufacturer:
Sede Produttiva/** Production Site: **Via Don G. Dossetti , 5/7 – 46023 Gonzaga loc. Palidano (MN) ITALIA

per il dispositivo/i *for the device(s)*

(vedi allegato tecnico/ see technical sheet)*

è conforme ai requisiti applicabili della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni.

is in compliance with the applicable requirements of Council Directive 93/42/EEC and subsequent modifications and integrations.

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* **L'allegato tecnico è parte integrante del presente Certificato**
The technical sheet is an integral part of this Certificate.

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Aghi per mesoterapia, sterile/Mesotherapy needles, sterile	*MXXYYYZZ*[1]
Aghi per intralipoterapia/ Intralipotherapy needles, sterile	*MILTXXYYY*[2]
Aghi per elettrolipolisi, sterile/Electrolipolysis needles, sterile	*MLPXXXY*[3]
Raccordi multiniettori senza aghi, sterile/Multinjectors, sterile	*MRYXXX*[4]
Raccordi multiniettori con aghi, sterile/Multinjectors with needles, sterile	*MRYYXXX*[5]
Set per mesoterapia senza ago, sterile/Mesotherapy set, sterile	*MDHNXXX*[6]
Set per mesoterapia con ago, sterile/Mesotherapy set with needles,, sterile	*MDHNXXYYZ*[7]
Iniettore monouso per microterapia, sterile/Skin injection therapy, sterile	*MSITXXXY*[8]
Set "Bont Kit" con siringa, ago di prelievo e ago intradermico/"Bont Kit" set with syringe, drawing needle and intradermal needle	*M03SBK*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Rubinetti / Stopcocks	*AAXXYYYYYY*[9]
Tappi di chiusura/ Closing cap	*AAXXYYYYYY*[9] *020440611000000* *020440621000000*
Rampe / Manifolds	*AAXXYYYYYY*[9]
Raccordi / Connectors	*AAXXYYYYYY*[9]
Valvole/ Valves	*AAXXYYYYYY*[9]
Prolunghe/Extension lines	*AAXXYYYZZZZ*[10]
	A15L150AA
Deflussori/ Infusion and transfusion sets	*DXXXYYYY*[11]

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Tubi di connessione per aspirazione, non sterile/ Aspiration tube, non sterile *Set tubi per apparecchiature di dermabrasione, sterile / Set tubes for dermabrasion equipment, sterile*	*EXXYYYYYY*[12]
Drenaggio toracico, sterile/ Thoracic drainage, sterile	*EXXYYYYYY*[12]
Set per drenaggio toracico, sterile/ Thoracic drainage set, sterile	*EXXYYYYYY*[12]

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Catetere arterioso, sterile/ Arterial catheter, sterile	*ACXXYYY*[13]
Catetere arterioso con prolunga, sterile/ Arterial catheter with extension line, sterile	*APXXYYY*[13]

***Classe IIa** (Class IIa)*

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Cannula endotimpanica, sterile/ Endotympanic cannula,sterile	*COXXCYY*[14]
Mascherina nasale, sterile/ Nasal mask, sterile	*COXXMYYS*[14]
Mascherina nasale, non sterile/ Nasal mask, non sterile	*COXXMYY*[14]
Doccia nasale, non sterile/ Nasal irrigation, non sterile	*COXXDYY*[14]
Forcella nasale, non sterile/ Nasal fork, non sterile	*COXXFYY*[14]
Oliva nasale, non sterile/ Nasal olive, non sterile	*COXXOYY*[14]
Boccaglio, non sterile/ Mouthpiece, non sterile	*COXXBYY*[14]

[redacted]

The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

ALLEGATO TECNICO — TECHNICAL SHEET

Il Certificato n° / *The Certificate no.* **QPZ-1916-19**

Addendum n° / *addendum no.* *//-//*

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

[1]M: lettera che individua il gruppo di appartenenza; XX: numeri che indicano la destinazione d'uso; YYY: campo alfanumerico che indica il diametro dell'ago; ZZ: numeri che indicano la lunghezza

[2]M: lettera che individua il gruppo di appartenenza; ILT: lettere che indicano la destinazione d'uso; XX: numeri che indicano il diametro dell'ago; YYY: numeri che indicano la lunghezza

[3]M: lettera che individua il gruppo di appartenenza; LP: lettere che indicano la destinazione d'uso; XXX: numeri che indicano la lunghezza; Y: lettera che indica eventuale zona di distribuzione

[4]M: lettera che individua il gruppo di appartenenza; R: lettera che indica il tipo; Y: lettera che indica il modello; XXX: numeri che indicano la configurazione

[5]M: lettera che individua il gruppo di appartenenza; R: lettera che indica il tipo; YY: lettere che indicano il modello; XXX: numeri che indicano la configurazione

[6]M: lettera che individua il gruppo di appartenenza; DHN: lettere che indicano il tipo; XXX: lettere che indicano il modello

[7]M: lettera che individua il gruppo di appartenenza; DHN: lettere che indicano il tipo; XX: numeri che indicano il diametro dell'ago; YY: numeri che indicano la lunghezza; Z: lettera che indica eventuale distributore;

[8]M: lettera che individua il gruppo di appartenenza; SIT: lettere che indicano il tipo; XXX: numeri che indicano il modello; Y: lettera che indica eventuale zona di distribuzione;

[9]AA: lettere che individuano il gruppo di appartenenza (Accessori); XX: numeri che definiscono il modello; YYYYYY: campo alfanumerico (variabile da 1 a 6 caratteri) che indica la configurazione;

[10]AA: lettere che individuano il gruppo di appartenenza (Prolunghe); XX: numeri che definiscono il modello; YYY: numeri che indicano la lunghezza; ZZZZ: campo alfanumerico (variabile da 0 a 4 caratteri) che indica la configurazione

[11]D: indica il gruppo di appartenenza (Deflussori); XXX: campo alfanumerico che indica il modello; YYYY: campo alfanumerico (variabile da 0 a 4 caratteri) che indica la configurazione;

[12]E: indica il gruppo di appartenenza; XX: numeri che indicano il modello; YYYYYY: campo alfanumerico (variabile da 4 a 6 caratteri) che indicano le varianti del modello;

[13]AC/AP: lettere che individuano il tipo; XX: numeri che indicano il diametro; YYY: campo alfanumerico che indica le varianti;

[14]CO: lettere che indicano il gruppo di appartenenza; XX: numeri che indicano il tipo; C: indica la cannula; M: indica la mascherina nasale; D: indica la doccia nasale; F: indica la forcella nasale; O: indica l'oliva nasale; B: indica il boccaglio; S: indica lo speculum; YY: lettere che indicano le varianti. Nel caso di mascherina nasale S indica sterile.

Valutazione della Conformità: vedi MOD-341-01-01 n. 343/19
Conformity assessment: see MOD-341-01-01 n. 343/19

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

M.V. s.r.l.
ARTICOLI BIOMEDICALI

For the Kind Attention of
PLASTIMED Gmbh
Lebacher Str.4 D-66113 Saarbrücken
Germania

Declaration of Conformity	**N°**	**17157**	**date**	**20/12/2017**

We hereby declare that:

Articles:	**Code:**
ARTERIOSELD FEP XRO3cmx0.7+ARTERIOSELD 4F C/PROL.INTEGRATA mm140	AC07030 ART.422032 + AP13140 ART.422R144
DOPPIA VALVOLA DI HEIMLICH+ARTERIOSELD 3F C/PROL.INTEGRATA mm80x3Fr	AA37HVCF2 ART.691526 + AP10080 ART.422R083
ARTERIOSELD 3Fmm60 + KIT DRENAGGIO TORACICO Ø 2.7mm L50cm	AP10060 ART.422R063 + E02K0850 ART.301K508
DRENAGGIO TORACICO PE XRO Ø2.7mm L50cm+DRENAGGIO TORACICO PE XRO Ø2.7mmx50cm	E020850 ART.301508+ E020850S ART.301S508
ARTERIOSELD 3F C/PROL. INTEGRATA+PONTE XRO 140mm	AP10140 ART.422R143
ARTERIOSELD C/PROL. INTEGRATA+PONTE PTFE mm40	AP10040 ART.422R043

Batch: 17157 **Expiration Date: 2022-10**

STERILIZATION NUMBER: 17121201

CE Certificate Validity Check ~~Yes~~ No

Conform to the provisions of the current Directive 93/42/CEE, concerning Medical Devices and therefore bears the CE mark of conformity on its labeling in combination with the Notified Body identification number 0373 of Italian Istituto Superiore di Sanità, Rome, Italy.

Conformity to the applicable Essential Requirements for safety and performance per current Directive 93/42/CEE, Annex I: "Essential Requirements" has been proved, so it offers the benefits granted and it is guaranteed the absence of commitment to health and safety of people, provided that the product is used according to the intended purpose.

The device classification (class IIa, sterile) has been determined per current Directive 93/42/CEE, Annex IX: "Classification criteria".

MV's Quality Management System fulfils the Quality Management System requirements described in the current Directive 93/42/CEE and ISO 13485, as evidenced by the UNI EN ISO 13485:2013 Certificate No. 6549 – M. The specified medical device falls within the scope of MV's Quality Management System as indicated in the certificate.

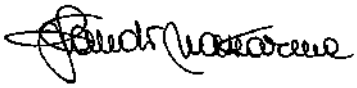
This declaration of Conformity is valid until September 09, 2019, the validity indicated on the CE Approval of Quality Assurance System for Production and/or Sterilization n. QPZ-1739-14.

Sede Legale: Via F.lli Cervi, 7 – 46023 GONZAGA loc. PALIDANO (MN) – ITALY - Tel. +39-0376-536995 – Fax +39-0376-530441
Sede Amministrativa e stabilimento: Via Don G. Dossetti, 5/7 – 46023 GONZAGA loc. PALIDANO (MN) ITALY
Società unipersonale – E-mail: info@mvsrl.it – web site: www.mvsrl.it
Cod. Fisc. e Partita IVA IT 01913020200 – R.E.A. MN n.208569
Reg.Imprese n. 01913020200 di Mantova – Cap. Soc. € 93.600,00 i.v.

M.V. s.r.l.
ARTICOLI BIOMEDICALI

Place of Issue: Gonzaga (MN), Italy

LR
Nazzarena Grandi



Reference to our DDT N. 1274 of 11/12/2017

Sede Legale: Via F.lli Cervi, 7 – 46023 GONZAGA loc. PALIDANO (MN) – ITALY - Tel. +39-0376-536995 – Fax +39-0376-530441
Sede Amministrativa e stabilimento: Via Don G. Dossetti, 5/7 – 46023 GONZAGA loc. PALIDANO (MN) ITALY
Società unipersonale – E-mail: info@mvsrl.it – web site: www.mvsrl.it
Cod. Fisc. e Partita IVA IT 01913020200 – R.E.A. MN n.208569
Reg.Imprese n. 01913020200 di Mantova – Cap. Soc. € 93.600,00 i.v.

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 23818 rev. 10**
Délivrée à Paris le 21 février 2019
Issued in Paris on February 21st, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
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
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*

PRODIMED
6 rue Louis Armand
95130 LE PLESSIS BOUCHARD FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.

sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600032, 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 P600032, 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

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 :* **February 21st, 2019 (included)**
Valable jusqu'au / *Expiry date :* **August 15th, 2022 (included)**

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_0293-F-V9-07-2016

GMED - 23818 rev. 10
Renouvelle le certificat 23818-9

GMED
GROUPE LNE

Addendum au certificat n° 23818 rev. 10 **page 1/1**
Addendum of the certificate n° 23818 rev. 10
Dossier / *File* N° P600032

Identification des dispositifs / *Identification of devices*

Version française :
Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.

- **Cathéters artériels périphériques stériles à usage unique**
- **Cathéters veineux périphériques stériles à usage unique**
- **Cathéters veineux périphériques à aiguille stériles à usage unique**
- **Aiguilles stériles à usage unique**
- **Drainage abdominal et thoracique stériles à usage unique**

Version anglaise :
Sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.

- ***Sterile single use arterial catheters for peripheral use***
- ***Sterile single use peripheral venous catheters***
- ***Sterile single use peripheral venous catheters with needle***
- ***Sterile single use needles***
- ***Sterile single use abdominal and thoracic drainage devices***

Les produits couverts par ce certificat sont référencés sur la liste des produits de PRODIMED (3 pages) datée du 14 février 2019, authentifiée par GMED en date du 19 février 2019

Medical devices covered by this certificate are referenced on the PRODIMED's list of products (3 pages) dated February 14th, 2019, authenticated by GMED on February 19th, 2019

Ce certificat couvre le site et les activités suivants
This certificate covers the following site and activities

- **PRODIMED – 6 rue Louis Armand 95130 LE PLESSIS BOUCHARD FRANCE**
  Siège social – Activités de conception, de fabrication et de contrôle final / *Headquarters – Design, manufacturing and final inspection activities*

GMED | 0459

On behalf of the President
Béatrice LYS
Technical Director

LISTE DES PRODUITS/LIST OF PRODUCTS
Annexe II excluant le point 4 Directive 93/42/CEE
Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Cathéters **artériels** (ombilicaux) périphériques stériles à usage **unique**
Cathéters **veineux** (ombilicaux) périphériques stériles à usage **unique**

Sterile single use arterial **(umbilical)** catheter for peripheral use
Sterile single use **peripheral venous** (umbilical) catheter

REFERENCE	DESIGNATION	CLASSE
1183.12	OMBILICATH 3,5 F	II b
1194.12	OMBILICATH 3,5F PU 40 cmx 1,2 mm	II b
11621.13	OMBILICATH 4F - 2L PU 15 cm x 1,3 mm	II b
11622.13	OMBILICATH 4F - 2L PU 20 cm x 1,3 mm	II b
11623.13	OMBILICATH 4F - 2L PU 30 cm x 1,3 mm	II b
1183.17	OMBILICATH 5F	II b
11623.17	OMBILICATH 5F - 2L PU 30 cm x 1,7 mm	II b
1194.17	OMBILICATH 5F PU 40 cm x 1,7 mm	II b
1183.23	OMBILICATH 7F PU 30 cm x 2,3 mm	II b

Cathéters veineux périphériques à aiguille stériles à usage unique

Sterile single use Peripheral venous catheters with needle

REFERENCE	DESIGNATION	CLASSE
1244.13	ENDOCATH 40CM X 1.3MM 4F	II b
1246.13	ENDOCATH 60CM X 1.3MM 4F	II b
1246.15	ENDOCATH 60CM X 1.5MM 4.5F	II b

GMED (0459) reconnait que son certificat CE
est valide pour les dispositifs médicaux décrits
..... 19 FEV. 2019
GMED (0459) recognizes that its EC certificate
is valid for the medical devices listed

14/02/2019

PRODIMED S.A.S. ETABLISSEMENT SECONDAIRE
ZAE, 6 rue Louis Armand - 95130 LE PLESSIS BOUCHARD France - Tél. 33 (0)1 34 44 15 15 - Fax 33 (0)1 30 72 22 08
Siret : 324 918 283 00031
PRODIMED S.A.S. SIEGE SOCIAL
ZI, 4 avenue de l'Europe - 60530 NEUILLY EN THELLE - France - Tél. 33 (0)3 44 26 63 46 - Fax 33 (0)3 44 26 93 37
Site Internet : www.prodimed.com e-mail : contact@prodimed.com
S.A.S. au capital de 728 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023
PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

LISTE DES PRODUITS/LIST OF PRODUCTS
Annexe II excluant le point 4 Directive 93/42/CEE
Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Cathéters artériels périphériques stériles à usage unique

Sterile single use Arterial catheters for peripheral use

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits 19 FEV. 2019

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed

REFERENCE	DESIGNATION	CLASSE
3842.09	SELDICATH PU EXTENSION 4CM 20G 0.9MM	II b
3843.09	SELDICATH PU EXTENSION 6CM 20G 0.9MM	II b
3843.12	SELDICATH PU EXTENSION 6CM 18G 1.2MM	II b
3844.09	SELDICATH PU EXTENSION 8CM 20G 0.9MM	II b
3844.12	SELDICATH PU EXTENSION 8CM 18G 1.2MM	II b
3846.09	SELDICATH PU EXTENSION 11CM 20G 0.9MM	II b
3846.12	SELDICATH PU EXTENSION 11CM 18G 1.2MM	II b
3848.12	SELDICATH PU EXTENSION 15CM 18G 1.2MM	II b
3849.12	SELDICATH PU EXTENSION 20CM 18G 1.2MM	II b
3871.07	SELDICATH FEP 2CM 22G 0.7MM	II b
3871.10	SELDICATH PTFE 2CM 20G 1.0MM	II b
3872.07	SELDICATH FEP 3CM 22G 0.7MM	II b
3872.10	SELDICATH PTFE 4CM 20G 1.0MM	II b
3872.13	SELDICATH PTFE 4CM 18G 1.3MM	II b
3873.10	SELDICATH PTFE 6CM 20G 1.0MM	II b
3873.13	SELDICATH PTFE 6CM 18G 1.3MM	II b
3874.10	SELDICATH PTFE 8CM 20G 1.0MM	II b
3874.13	SELDICATH PTFE 8CM 18G 1.3MM	II b
3874.17	SELDICATH PTFE 8CM 16G 1.7MM	II b
3874C10	SELDICATH PTFE 8CM 20G 1.0MM AIG.COURTE	II b
3876.10	SELDICATH PTFE 11CM 20G 1.0MM	II b
3876.13	SELDICATH PTFE 11CM 18G 1.3MM	II b
3876.17	SELDICATH PTFE 11CM 16G 1.7MM	II b
3876.20	SELDICATH PTFE 11CM 14G 2.0MM	II b
3881.10	SELDICATH PTFE 15CM 20G 1.0MM	II b
3881.13	SELDICATH PTFE 15CM 18G 1.3MM	II b
3881.13L	SELDICATH PTFE 15CM 18G 1.3MM AIG.LONG	II b
3882.10	SELDICATH PTFE 20CM 20G 1.0MM	II b
3882.13	SELDICATH PTFE 20CM 18G 1.3MM	II b
3882.17	SELDICATH PTFE 20CM 16G 1.7MM	II b
3882.20	SELDICATH PTFE 20CM 14G 2.0MM	II b
3883.10	SELDICATH PTFE 30CM 20G 1.0MM	II b
3883.13	SELDICATH PTFE 30CM 18G 1.3MM	II b
3883.17	SELDICATH PTFE 30CM 16G 1.7MM	II b
3883.20	SELDICATH PTFE 30CM 14G 2.0MM	II b

Vu

14/02/2019

PRODIMED S.A.S. ETABLISSEMENT SECONDAIRE
ZAE, 6 rue Louis Armand - 95130 LE PLESSIS BOUCHARD France - Tél. 33 (0)1 34 44 15 15 - Fax 33 (0)1 30 72 22 08
Siret : 324 918 283 00031

PRODIMED S.A.S. SIEGE SOCIAL
ZI, 4 avenue de l'Europe - 60530 NEUILLY EN THELLE - France - Tél. 33 (0)3 44 26 63 46 - Fax 33 (0)3 44 26 93 37
Site Internet : www.prodimed.com e-mail : contact@prodimed.com
S.A.S. au capital de 728 000 euros - RCS Compiègne B 324 918 283 - Code APE 3250A - Siret : 324 918 283 00023

PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

LISTE DES PRODUITS/LIST OF PRODUCTS
Annexe II excluant le point 4 Directive 93/42/CEE
Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Aiguilles stériles à usage unique

Sterile single use needles

REFERENCE	DESIGNATION	CLASSE
1915.10	MICRODARD 55MM POUR CATHETER 1.0MM	II a
1917.20	MICRODARD 75MM POUR CATHETER 2.0MM	II a
1935.07	MICRODARD 5CM DIA.INT 0.7MM	II a
1938.10	MICRODARD 8CM DIA.INT 1.0MM	II a
1938.13	MICRODARD 8CM DIA.INT 1.3MM	II a
2917.10	MICRODARD 7CM MANDRIN INOX 1.0MM	II a
8752.10	DISP BLOC PARA-CERVICAL DEPASST AIG46MM	II a
8755.10	DISP BLOC PARA-CERVICAL DEPASST AIG 6MM	II a

Drainage abdominal stérile à usage unique

Sterile single use Abdominal drainage devices

REFERENCE	DESIGNATION	CLASSE
6837.10	MICRODARD PONCTION D'ASCITE 7CM	II a

Drainage thoracique stérile à usage unique

Sterile single use thoracic drainage devices

REFERENCE	DESIGNATION	CLASSE
5323.20	PLEUROCATH NEONATAL 30CM X 2.0MM 6F	II a
5324.27	PLEUROCATH PEDIATRIE 40CM X 2.7MM 8F	II a
5325.27	PLEUROCATH ADULTES 50CM X 2.7MM 8F	II a
5325.33	PLEUROCATH ADULTES 50CM X 3.3MM 10F	II a
5325P33	PLEUROCATH ADULTES 50CM X 3.3MM 10F	II a
5334.27	PLEUROCATH SAMU 40CM X 2.7MM 8F	II a
5343.20	PLEUROCATH SELDINGER 25CM X 2MM 6F	II a
5344.27	PLEUROCATH SELDINGER 40CM X 2.7MM 8F	II a
5344.33	PLEUROCATH SELDINGER 40CM X 3.3MM 10F	II a
5344.40	PLEUROCATH SELDINGER 40CM X 4.0MM 12F	II a
5354.40	PLEUROCATH SELDINGER 40CM 12F/AIG TUOHY	II a
5375.27	PLEUROCATH GUIBOUT 50CM X 2.7MM 8F	II a

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed
GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux écrits
19 FEV. 2019

14/02/2019

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GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 23818 rev. 10**
Délivrée à Paris le 21 février 2019
Issued in Paris on February 21st, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
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
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*

PRODIMED
6 rue Louis Armand
95130 LE PLESSIS BOUCHARD FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.

sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600032, 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 P600032, 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

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 :* **February 21st, 2019 (included)**
Valable jusqu'au / *Expiry date :* **August 15th, 2022 (included)**

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_0293-F-V9-07-2016

GMED - 23818 rev. 10
Renouvelle le certificat 23818-9

GMED
GROUPE LNE

Addendum au certificat n° 23818 rev. 10 **page 1/1**
Addendum of the certificate n° 23818 rev. 10
Dossier / *File* N° P600032

Identification des dispositifs / *Identification of devices*

Version française :
Dispositifs médicaux stériles comprenant des dispositifs pour l'accès vasculaire, l'accès gastro-intestinal, le drainage, le prélèvement, la gynécologie et l'obstétrique.

- **Cathéters artériels périphériques stériles à usage unique**
- **Cathéters veineux périphériques stériles à usage unique**
- **Cathéters veineux périphériques à aiguille stériles à usage unique**
- **Aiguilles stériles à usage unique**
- **Drainage abdominal et thoracique stériles à usage unique**

Version anglaise :
Sterile medical devices including devices for vascular access, gastro-intestinal access, drainage and sampling, gynaecological and obstetric procedures.

- ***Sterile single use arterial catheters for peripheral use***
- ***Sterile single use peripheral venous catheters***
- ***Sterile single use peripheral venous catheters with needle***
- ***Sterile single use needles***
- ***Sterile single use abdominal and thoracic drainage devices***

Les produits couverts par ce certificat sont référencés sur la liste des produits de PRODIMED (3 pages) datée du 14 février 2019, authentifiée par GMED en date du 19 février 2019

Medical devices covered by this certificate are referenced on the PRODIMED's list of products (3 pages) dated February 14th, 2019, authenticated by GMED on February 19th, 2019

Ce certificat couvre le site et les activités suivants
This certificate covers the following site and activities

- **PRODIMED – 6 rue Louis Armand 95130 LE PLESSIS BOUCHARD FRANCE**
  Siège social – Activités de conception, de fabrication et de contrôle final / *Headquarters – Design, manufacturing and final inspection activities*

GMED | 0459

On behalf of the President
Béatrice LYS
Technical Director

LISTE DES PRODUITS/LIST OF PRODUCTS
Annexe II excluant le point 4 Directive 93/42/CEE
Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Cathéters **artériels** (ombilicaux) périphériques stériles à usage **unique**
Cathéters **veineux** (ombilicaux) périphériques stériles à usage **unique**

Sterile single use arterial **(umbilical)** catheter for peripheral use
Sterile single use **peripheral venous** (umbilical) catheter

REFERENCE	DESIGNATION	CLASSE
1183.12	OMBILICATH 3,5 F	II b
1194.12	OMBILICATH 3,5F PU 40 cmx 1,2 mm	II b
11621.13	OMBILICATH 4F - 2L PU 15 cm x 1,3 mm	II b
11622.13	OMBILICATH 4F - 2L PU 20 cm x 1,3 mm	II b
11623.13	OMBILICATH 4F - 2L PU 30 cm x 1,3 mm	II b
1183.17	OMBILICATH 5F	II b
11623.17	OMBILICATH 5F - 2L PU 30 cm x 1,7 mm	II b
1194.17	OMBILICATH 5F PU 40 cm x 1,7 mm	II b
1183.23	OMBILICATH 7F PU 30 cm x 2,3 mm	II b

Cathéters veineux périphériques à aiguille stériles à usage unique

Sterile single use Peripheral venous catheters with needle

REFERENCE	DESIGNATION	CLASSE
1244.13	ENDOCATH 40CM X 1.3MM 4F	II b
1246.13	ENDOCATH 60CM X 1.3MM 4F	II b
1246.15	ENDOCATH 60CM X 1.5MM 4.5F	II b

GMED (0459) reconnait que son certificat CE
est valide pour les dispositifs médicaux décrits
..... 19 FEV. 2019
GMED (0459) recognizes that its EC certificate
is valid for the medical devices listed

14/02/2019

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PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

LISTE DES PRODUITS/LIST OF PRODUCTS
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Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Cathéters artériels périphériques stériles à usage unique

Sterile single use Arterial catheters for peripheral use

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits 19 FEV. 2019

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed

REFERENCE	DESIGNATION	CLASSE
3842.09	SELDICATH PU EXTENSION 4CM 20G 0.9MM	II b
3843.09	SELDICATH PU EXTENSION 6CM 20G 0.9MM	II b
3843.12	SELDICATH PU EXTENSION 6CM 18G 1.2MM	II b
3844.09	SELDICATH PU EXTENSION 8CM 20G 0.9MM	II b
3844.12	SELDICATH PU EXTENSION 8CM 18G 1.2MM	II b
3846.09	SELDICATH PU EXTENSION 11CM 20G 0.9MM	II b
3846.12	SELDICATH PU EXTENSION 11CM 18G 1.2MM	II b
3848.12	SELDICATH PU EXTENSION 15CM 18G 1.2MM	II b
3849.12	SELDICATH PU EXTENSION 20CM 18G 1.2MM	II b
3871.07	SELDICATH FEP 2CM 22G 0.7MM	II b
3871.10	SELDICATH PTFE 2CM 20G 1.0MM	II b
3872.07	SELDICATH FEP 3CM 22G 0.7MM	II b
3872.10	SELDICATH PTFE 4CM 20G 1.0MM	II b
3872.13	SELDICATH PTFE 4CM 18G 1.3MM	II b
3873.10	SELDICATH PTFE 6CM 20G 1.0MM	II b
3873.13	SELDICATH PTFE 6CM 18G 1.3MM	II b
3874.10	SELDICATH PTFE 8CM 20G 1.0MM	II b
3874.13	SELDICATH PTFE 8CM 18G 1.3MM	II b
3874.17	SELDICATH PTFE 8CM 16G 1.7MM	II b
3874C10	SELDICATH PTFE 8CM 20G 1.0MM AIG.COURTE	II b
3876.10	SELDICATH PTFE 11CM 20G 1.0MM	II b
3876.13	SELDICATH PTFE 11CM 18G 1.3MM	II b
3876.17	SELDICATH PTFE 11CM 16G 1.7MM	II b
3876.20	SELDICATH PTFE 11CM 14G 2.0MM	II b
3881.10	SELDICATH PTFE 15CM 20G 1.0MM	II b
3881.13	SELDICATH PTFE 15CM 18G 1.3MM	II b
3881.13L	SELDICATH PTFE 15CM 18G 1.3MM AIG.LONG	II b
3882.10	SELDICATH PTFE 20CM 20G 1.0MM	II b
3882.13	SELDICATH PTFE 20CM 18G 1.3MM	II b
3882.17	SELDICATH PTFE 20CM 16G 1.7MM	II b
3882.20	SELDICATH PTFE 20CM 14G 2.0MM	II b
3883.10	SELDICATH PTFE 30CM 20G 1.0MM	II b
3883.13	SELDICATH PTFE 30CM 18G 1.3MM	II b
3883.17	SELDICATH PTFE 30CM 16G 1.7MM	II b
3883.20	SELDICATH PTFE 30CM 14G 2.0MM	II b

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PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

LISTE DES PRODUITS/LIST OF PRODUCTS
Annexe II excluant le point 4 Directive 93/42/CEE
Annex II excluding section 4 Directive 93/42/EEC

PRODIMED

Aiguilles stériles à usage unique

Sterile single use needles

REFERENCE	DESIGNATION	CLASSE
1915.10	MICRODARD 55MM POUR CATHETER 1.0MM	II a
1917.20	MICRODARD 75MM POUR CATHETER 2.0MM	II a
1935.07	MICRODARD 5CM DIA.INT 0.7MM	II a
1938.10	MICRODARD 8CM DIA.INT 1.0MM	II a
1938.13	MICRODARD 8CM DIA.INT 1.3MM	II a
2917.10	MICRODARD 7CM MANDRIN INOX 1.0MM	II a
8752.10	DISP BLOC PARA-CERVICAL DEPASST AIG46MM	II a
8755.10	DISP BLOC PARA-CERVICAL DEPASST AIG 6MM	II a

Drainage abdominal stérile à usage unique

Sterile single use Abdominal drainage devices

REFERENCE	DESIGNATION	CLASSE
6837.10	MICRODARD PONCTION D'ASCITE 7CM	II a

Drainage thoracique stérile à usage unique

Sterile single use thoracic drainage devices

REFERENCE	DESIGNATION	CLASSE
5323.20	PLEUROCATH NEONATAL 30CM X 2.0MM 6F	II a
5324.27	PLEUROCATH PEDIATRIE 40CM X 2.7MM 8F	II a
5325.27	PLEUROCATH ADULTES 50CM X 2.7MM 8F	II a
5325.33	PLEUROCATH ADULTES 50CM X 3.3MM 10F	II a
5325P33	PLEUROCATH ADULTES 50CM X 3.3MM 10F	II a
5334.27	PLEUROCATH SAMU 40CM X 2.7MM 8F	II a
5343.20	PLEUROCATH SELDINGER 25CM X 2MM 6F	II a
5344.27	PLEUROCATH SELDINGER 40CM X 2.7MM 8F	II a
5344.33	PLEUROCATH SELDINGER 40CM X 3.3MM 10F	II a
5344.40	PLEUROCATH SELDINGER 40CM X 4.0MM 12F	II a
5354.40	PLEUROCATH SELDINGER 40CM 12F/AIG TUOHY	II a
5375.27	PLEUROCATH GUIBOUT 50CM X 2.7MM 8F	II a

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed
GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux écrits
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PRODIMED

EC DECLARATION OF CONFORMITY

Manufacturer's Name: **PRODIMED**

Address : 6, Rue Louis Armand
95130 Le Plessis Bouchard
France

Declares that the medical device ranges described hereafter (details below):

Sterile single-use arterial catheter for peripheral use
Seldicath®

- are in conformity with the essential requirements and provisions of European Directive 93/42/EEC dated June 14th 1993 transcribed in French law by the Decrees n° 95-292, n° 2009-482 and n° 2010-270,

- are subjected to the procedure in Annex II (excluding Section 4) of European Directive 93/42/EEC under the supervision of Notified Body Number 0459 :

  LNE – G-MED
  Laboratoire National de Métrologie et d'Essais
  1, rue Gaston Boissier
  75724 PARIS Cedex15

This declaration is based on various elements as:

- **V63** technical record information demonstrates the conformity with essential requirements of the 93/42/CEE directive.

- The certificate N° **23831** issued by our notified body (LNE-GMed) certifies Quality Management System developed by PRODIMED complies with the requirements of the international standards ISO 13485: 2003 – NF EN ISO 13485 : 2012.

- The certificate N° **23818** issued by our notified body (LNE-GMed) certifies that Quality System for design, manufacturing and final inspection complies with the requirements of the Directive 93/42/EEC, Annex II excluding section 4.

Le Plessis Bouchard, January 4th 2018

Patrick CHAULET
General Manager

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PRODUCTION DE MATERIEL MEDICO - CHIRURGICAL

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Déclaration CE de conformité / **EC Declaration of conformity**

Référence commerciale	Désignation	Classe
3842.09	Seldicath PU 4 cm x 0,9 mm : 20G	II b
3843.09	Seldicath 0,9 mm PU 6 cm x 0,9 mm : 20G	II b
3843.12	Seldicath	II b
3844.09	Seldicath	II b
3844.12	Seldicath	II b
3846.09	Seldicath 0,9 mm PU 11 cm x 0,9 mm : 20G	II b
3846.12	Seldicath 1,2 mm PU 11 cm x 1,2 mm : 18G	II b
3848.12	Seldicath PU 15 cm x 1,2 mm : 18G	II b
3849.12	Seldicath 1,2 PU 20 cm x 1,2 mm 18G	II b
3854 10	Seldicath PU 8 cm x 0,9 mm : 20G	II b
3854 13	Seldicath PU 8 cm x 1,2 mm : 18G	II b
3856 10	Seldicath PU 11 cm x 0,9 mm : 20G	II b
3856 13	Seldicath PU 11 cm x 1,2 mm	II b
3871.07	Seldicath 2F FEP 2 cm x 0,7 mm	II b
3871.10	Seldicath 3F PTFE 2 cm x 1,0 mm	II b
3872.07	Seldicath 2F FEP 3 cm x 0,7 mm	II b
3872.10	Seldicath 3F PTFE 4 cm x 1,0 mm	II b
3872.13	Seldicath 4F PTFE 4 cm x 1,3 mm	II b
3873.10	Seldicath 3F PTFE 6 cm x 1,0 mm	II b
3873.13	Seldicath 4F PTFE 6 cm x 1,3 mm	II b
3874.10	Seldicath 3F PTFE 8 cm x 1,0 mm	II b
3874.13	Seldicath 4F PTFE 8 cm x 1,3 mm	II b
3874.17	Seldicath 5F PTFE 8 cm x 1,7 mm	II b
3874C10	Seldicath 3F PTFE 8 cm x 1,0 mm	II b
3874S10	Seldicath 3F PTFE 8 cm x 1,0 mm	II b
3876.10	Seldicath 3F PTFE 11 cm x 1,0 mm	II b
3876.13	Seldicath 4F PTFE 11 cm x 1,3 mm	II b
3876.17	Seldicath 5F PTFE 11 cm x 1,7 mm	II b
3876.20	Seldicath 6F PTFE 11 cm x 2,0 mm	II b
3881.10	Seldicath 3F PTFE 15 cm x 1,0 mm	II b
3881.13	Seldicath 4F PTFE 15 cm x 1,3 mm	II b
3881.13L	Seldicath 4F PTFE 15 cm x 1,3 mm	II b
3882.10	Seldicath 3F PTFE 20 cm x 1,0 mm	II b
3882.13	Seldicath 4F PTFE 20 cm x 1,3 mm	II b
3882.17	Seldicath 5F PTFE 20 cm x 1,7 mm	II b
3882.20	Seldicath 6F PTFE 20 cm x 2,0 mm	II b
3883.10	Seldicath 3F PTFE 30 cm x 1,0 mm	II b
3883.13	Seldicath 4F PTFE 30 cm x 1,3 mm	II b
3883.17	Seldicath 5F PTFE 30 cm x 1,7 mm	II b
3883.20	Seldicath 6F PTFE 30 cm x 2,0 mm	II b

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