STERILE SUPPLY

Fog Free Solution & Pad

Product Function

The Fog Free solution & pad is used to prevent formation of condensation on the distal lens of the laparoscope.

Product Description

The disposable Fog Free pad & solution is a single use device, and is supplied sterile.
The Fog Free solution is a clear fluid supplied in an easy administration bottle & the soft foam pad prevents damage to the laparoscope lens.
Colour: White / Clear / Purple
Dimensions: Solution 6ml / Pad 50 x 50mm

Product Range

PS3500	Fog Free Solution & Pad

Standardisation

Device Classification (Defined by 93/42/EEC Directive)	Class IIA	Rule 6
CE Marking		CE 0120
GMDN		45225
Quality System Certified to		ISO13485:2003 & ISO9001:2008

Sterilisation

Supplied in Sterile Condition	YES
Sterilisation Method	Gamma Radiation
Product Shelf Life	4 years from date of sterilisation

Single Use Warning

These device(s) are designed and sold for single use only as defined in Article 1 (n) of directive 2007/47/EC. As such re-processing and, or, re-sterilisation after initial use is not permitted.

The effects of any unauthorized reprocessing or re sterilisation can result in the following complications:

1. Cross contamination due to ineffective re processing/re sterilisation.
2. Mechanical fatigue, and associated failure, due to the effects of the reprocessing / re sterilisation method.

Compatibility and Connectivity

The fog free solution is applied to the lens of an endoscope. There is no compatibility issue with this solution upon the glass/polycarbonate or acrylic lenses. However care should be taken in the force of application on any endoscope with plastic lens design due to the potential of scratching.

Product Materials

Components	Material	Grade	CAS#
Bottle	HDPE	MF6105PEX	9002-88-4
Cap	PP	MF5415	9003-07-0
Dropper	LDPE	MF4515	9002-88-4
Pad	PE-PU foam with barium chord thread on reverse underneath synthetic rubber adhesive with PE coated and siliconised paper release liner	Plastifoam 582C CAN.DO.5085M	N/A N/A
Fog Free Solution	Deionised Water	UNIVAR	7789-20-0
	Isopropanol	UNIVAR	67-63-0
	Surfactant	Kemsurf OT60	577-11-7/ 64-17-5

Materials Data

Latex Free	YES
Phthalate (DEHP, BBP & DBP) Free	YES

Unit Packaging	Blister (PA/ LDPE) with Lid (PET/ Peelable PE/ Laminating Adhesive)				
Box Packaging	Shelf Box		Shipping Carton		
Product Code	QTY. Pcs.	Dimensions, mm	Qty. Pcs.	Dimensions, mm	Gross Wt. Kg
PS3500	25	105 x 160 x 220	300	330 x 330 x 450	5.2

Disposal

After single patient use, the device is to be immediately disposed of as controlled medical waste.

Availability of Instructions for Use:

YES ☑ REF: Doc 11

NO ☐

Storage and Handling Instructions:

Store and Handle with Care

Document Revision History			
Revision	**Change detail**	**Date**	**Approved**
1	First Revision as part of paper copy DMF	2006	EH
2	Creation of Technical File Summary Document	2007-01	EH
3	Reclassification of device to class IIA & material updates	2010-06	JH
4	Update of details into new technical File summary document format & pad colour change to purple.	2010-11	JH
5	Introduction of Change history table and TFS Numbering system on the TFS template form	2014-02	JH

EC Certificate Full Quality Assurance System: Certificate GB19/964712

The management system of

Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited

2 Chestnut House, Farm Close, Shenley, Hertfordshire, WD7 9AD, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 05 May 2021 until 15 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 31 December 2002.

Certification is based on reports numbered GB/PC 207936

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Purple Surgical Holdings Limited
also known as
Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Sterile skin staplers, Sterile curettes, Non sterile oxygen tubes, Sterile and non sterile laparoscopic suction irrigation sets, Sterile and non sterile endoscopic and tissue retrieval pouches, Sterile and non sterile surgical secondary trocar, Sterile and non sterile laparoscopic aspiration needles, Sterile vessel loop, Sterile & non sterile insufflation filters, insufflation filter tubing sets, Sterile fog free solution and pad, Sterile and non sterile surgical primary trocars, Sterile and non sterile blunt dissectors, Nonsterile irrigation pumps, Sterile and non sterile, Veress needles, Sterile and non sterile electrosurgical pencils and electrodes, Sterile and non sterile electrosurgical laparoscopic scissors, graspers & forceps, Sterile and nonsterile laparoscopic electrosurgical electrodes, Sterile surgical staples and staplers, Class 1 sterile:sterility aspect only- restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile light handle covers, Sterile ultrasound probe covers, Sterile electrosurgical monopolar Cables, Sterile suction tubes & collection sets, Sterile uterine manipulator injectors, Sterile laparoscopic camera sleeve, Sterile skin markers, Sterile tip cleaners, Sterile skin staple removers, Sterile tube organiser holders ,Sterile Smoke evacuation filters and tubing sets, Sterile Laparoscopic Kits in accordance with the requirements of Directive 93/42/EEC Article 12.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Culmhead Business Centre, Culmhead, Taunton, Somerset, TA3 7DY, UK

Poole Works, Higher Poole, Wellington , Somerset, TA21 9HW, UK

Certificate GB02/58222

The management system of

Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited

2 Chestnut House Farm Close Shenley Hertfordshire WD7 9AD United Kingdom

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities
Design, manufacture, distribution of sterile and non-sterile single use and reusable Medical devices for general surgery, laparoscopic and gastro intestinal surgery, gynaecology, urology, obstetrics, bariatric surgery, vascular surgery, pleural surgery, ophthalmic surgery, radiology, dentistry, proctology, electrosurgical applications and post operative care
Servicing of the Irrigation pumps

This certificate is valid from 07 March 2024 until 07 March 2027 and remains valid subject to satisfactory surveillance audits.
Issue 18. Certified since 31 December 2002

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

UKAS MANAGEMENT SYSTEMS 0005

Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited

ISO 13485:2016

EN ISO 13485:2016

Issue 18
Sites
Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited 2 Chestnut House Farm Close Shenley Hertfordshire WD7 9AD United Kingdom HQ, Senior Management, International Regulatory Management, Marketing, and Customer Related Process
Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited Culmhead Business Centre Culmhead Taunton Somerset TA3 7DY United Kingdom Design, Manufacture, QA and inspections, Regulatory compliance, Clean Room manufacturing, Goods receipt inspections, Sterile Device Management, Inhouse injection, extrusion, packaging, labelling and dispatch. Distribution and Warehouse.
Purple Surgical Holdings Limited also known as Purple Surgical International Limited, Purple Surgical UK Limited and Purple Surgical Manufacturing Limited Poole Works Higher Poole Wellington Somerset TA21 9HW United Kingdom Warehouse and storage.

Purple Surgical Holdings Limited
Farm Close, 2 Chestnut House,
Shenley, Hertfordshire,
WD7 9AD
UK

17/05/2023

Confirmation Letter Reference: CLNB1639 GBPC225650

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

Purple Surgical Holdings Limited
Farm Close, 2 Chestnut House,
Shenley, Hertfordshire,
WD7 9AD
UK
SRN Number (if available): GB-MF-000012819

EU Rep:
Advena Ltd
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013, Malta
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 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 SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / 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
Class I Sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:	Class Is	N/A	GB19/964712; NB1639

Device name / 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
Sterile light handle covers; Sterile eye shields; Sterile ultrasound probe covers; Sterile electrosurgical monopolar cables; Sterile suction tubes & collection sets; Sterile uterine manipulator injectors; Sterile laparoscopic camera sleeve; Sterile skin markers; Sterile tip cleaners; Sterile skin staple removers; Sterile tube organiser holders; Sterile Smoke evacuation filters and tubing sets; 50512230LHCNN 50512230SUCTUBE&COLSETHW 50512230MONOPCABLESEW 50512230UTESPACKMAN 50512230TUBEORGANISER 50512230TIPCLEANERS 50512230SKINMARKERS 50512230CAMERASLEEVES 50512230SMOKEFILTERS 50512230ULTRASOUNDPC			
Sterile skin staplers; Sterile curettes; Sterile and non sterile laparoscopic suction irrigation sets; Sterile and non sterile endoscopic and tissue retrieval pouches; Sterile and non sterile surgical secondary trocar;	Class IIa	N/A	GB19/964712; NB1639

Device name / 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
Sterile and non sterile laparoscopic aspiration needles; Sterile vessel loop; Sterile fog free solution and pad; Sterile and non sterile surgical primary trocars; Sterile and non sterile blunt dissectors; Non-sterile irrigation pumps; Sterile and non sterile Veress needles Sterile Laparoscopic Kits in accordance with the requirements of Directive 93/42/EEC Article 12 50512230IRRIGATIONPUMPT4 50512230SECONDTROCARSDD 50512230TROKANGJIOPTPG 50512230TROCULTIMATEXL 50512230FOGFREE8F 50512230ASPIRNEEDLES6U 50512230VESSELLOOPSSG 50512230INSUFFFILTERSKK 50512230BLUNTDISSECTORSV 50512230TRPOUCHESGM 50512230SECURECATCHA2 50512230ERPOUCHES5U 50512230VERESSNEEDLESPZ 50512230CURETTEF&RMX 50512230SISET&PROBES83			
Sterile & non sterile insufflation filters, insufflation filter tubing sets Sterile and non sterile electrosurgical pencils and electrodes;	Class IIb	N/A	GB19/964712; NB1639

Device name / 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
Sterile and non sterile electrosurgical laparoscopic scissors, graspers & forceps; Sterile and nonsterile laparoscopic electrosurgical electrodes; Sterile surgical staples and staplers; Sterile Laparoscopic Kits in accordance with the requirements of Directive 93/42/EEC Article 12 50512230ESIBIPLINAE5 50512230ESIOPTCLA3G 50512230ESIMONVHMEDHP 50512230ESPENCIL&ELECTU6 50512230LAPELECTRODESV3 50512230SSLINEART8 50512230SSHAEMORRHRW 50512230SSCIRCUDSTTPT 50512230SSENDOLINEARJD 50512230CLIPAPPLIER3M 50512230ESIMONHANDLIKEE8 50512230SISET&PROGEYIAX			

Confirmation Letter Revision History

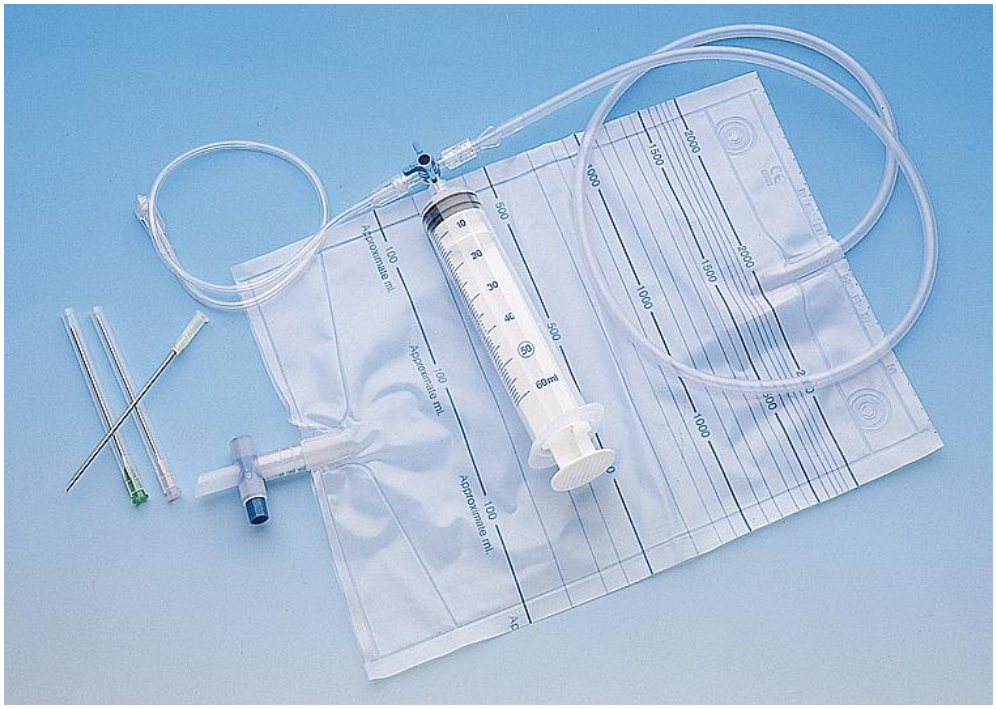
Date	NB internal reference traceable to each version of the letter	Action
2023/05/17	Version 1	Initial issue

67 p.d

CHIMED SISTEMI MEDICALI ITALIA

Thoracentesis
Paracentesis set

THORACENTESIS / PARACENTESIS SET WITH 3-WAY STOPCOCK



Three standard needles

Verres needle

- Each set includes all the accessories needed for immediate use
- Wide range of needles available
- Collection bag with cross outlet and non return valve
- Disposable, double packaged sterile

Cannula needle

Code	Description	Needle length	Bag capacity	Q.ty/box
MS/300/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	2000 ml	80
MS/300/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	2000 ml	80
MS/301/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	2000 ml	50
MS/306/size	Set with 1 cannula needle (various sizes/lengths)	----	2000 ml	50
MS/302/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	5000 ml	80
MS/302/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	5000 ml	80
MS/303/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	5000 ml	50
MS/307/size	Set with 1 cannula needle (various sizes/lengths)	----	5000 ml	50
MS/304/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	8000 ml	80
MS/304/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	8000 ml	80
MS/305/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	8000 ml	50
MS/308/size	Set with 1 cannula needle (various sizes/lengths)	----	8000 ml	50

THORACENTESIS / PARACENTESIS SET WITH TWO NON RETURN VALVES

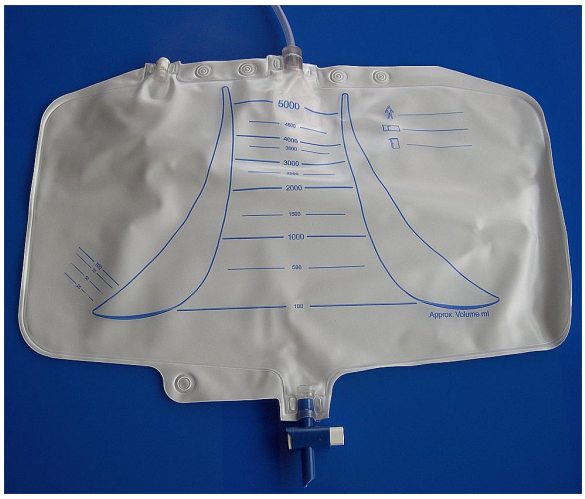
- Easy and fast operation thanks to two non return valves
- Ready to use set with wide choice of needles
- Collection bag with cross outlet and non return valve
- Disposable, double packaged, sterile

Code	Description	Needle length	Bag capacity	Q.ty/box
MS/300V/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	2000 ml	80
MS/300V/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	2000 ml	80
MS/301V/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	2000 ml	40
MS/306V/size	Set with 1 cannula needle (various sizes/lengths)	----	2000 ml	80
MS/302V/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	5000 ml	80
MS/302V/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	5000 ml	80
MS/303V/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	5000 ml	40
MS/307V/size	Set with 1 cannula needle (various sizes/lengths)	----	5000 ml	80
MS/304V/50	Set with 3 standard needles sizes G14, G16, G18	50 mm	8000 ml	80
MS/304V/80	Set with 3 standard needles sizes G14, G16, G18	80 mm	8000 ml	80
MS/305V/G	Set with 1 Verres needle size G14, G15 or G16	100 mm	8000 ml	40
MS/308V/size	Set with 1 cannula needle (various sizes/lengths)	----	8000 ml	40

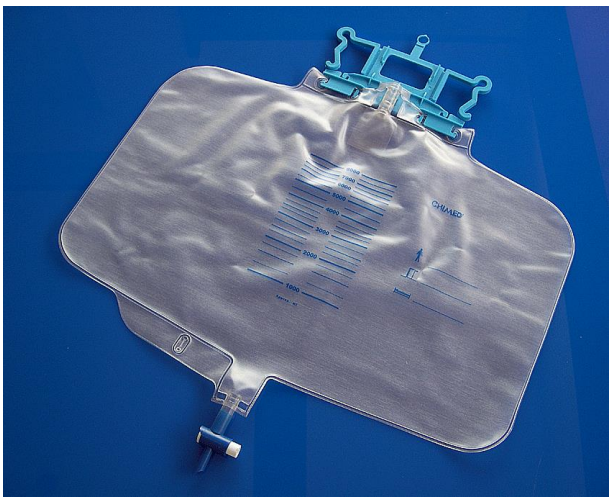
SPARE COLLECTION BAG

- Wide choice of bag capacities
- Each bag includes a non return valve and a cross outlet
- 90 cm connecting tube
- Disposable double packaged, sterile

2000 ml



5000 ml



8000 ml

Code	Description	Bag capacity	Connector	Q,ty/box
MS/00055P	Spare sterile collection bag, for set with 3-way stopcock, with female Luer Lock connector	2000 ml		100
MS/00058P		5000 ml		
MS/00059P		8000 ml		
MS/00055L	Spare sterile collection bag, for set with non return valves, with female Luer Lock connector	2000 ml		100
MS/00058L		5000 ml		
MS/00059L		8000 ml		

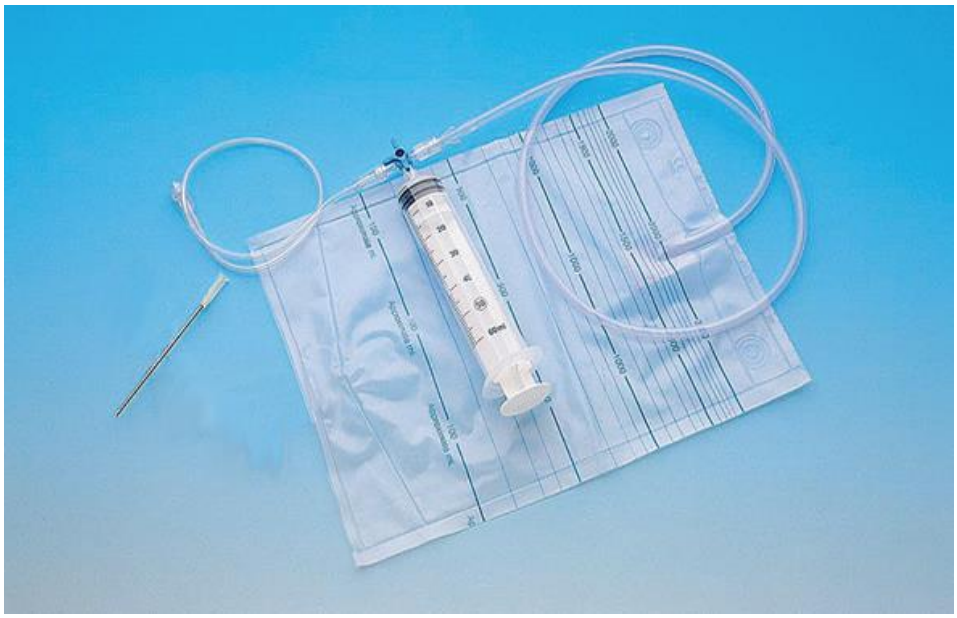
CE 0476

CHIMED

Via dell'Artigianato, 49 - 57121 Livorno (Italy) - Tel. +39 0586 427333
Fax +39 0586 427177 - e-mail: info@chimed.it–internet: www.chimed.it

CHIMED® MEDICAL SYSTEMS ITALY

Pleuros punkcijos rinkinys



- Sterilus
- Dviguba pakuotė
- Švirkštas 60ml
- Surinkimo maišas 2000ml su 90cm sujungimo vamzdeliu
- Trišakis kranelis su vienos krypties vožtuvu
- Trys adatos 80 mm: G14 -1 vnt, G16 -1 vnt, G18 -1 vnt

Chimed S.r.l.

Istituto Superiore di Sanità

Certificato n° *Certificate no.* **QPS-0535-20**

Addendum n° *addendum no.* //-//

Data prima emissione *First issue date*	**16.06.2020**
Data di emissione corrente *Current issue date*	**16.06.2020**
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 per i soli aspetti della fabbricazione che riguardano il raggiungimento e il mantenimento dello stato sterile
(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 for only the aspects of manufacture concerned with securing and maintaining sterile conditions
(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 per i soli aspetti della fabbricazione che riguardano il raggiungimento e il mantenimento dello stato sterile attuato da

The Istituto Superiore di Sanità, Notified Body 0373, certifies that the quality assurance system for only the aspects of manufacture concerned with securing and maintaining sterile conditions enforced by

CHIMED S.r.l.

***Sede Legale/** Registered Office:*
Via dell'Artigianato, 49 – 57121 Livorno (LI) 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

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

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QPS-0535-20**

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:

Nome prodotto *(Product name)*	***Codice*** *(Code)*
EURO *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1111XX; 1115XX*[1]
EUROPLUS *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1121XX; 1123XX*[1]
EUROPLUS TV *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1122XX; 1124XX*[1]
PERSONAL *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1131XX; 1132XX; 1134XX; 1135XX*[1]
PERSONAL Confort *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1133XX*[1]
EUROBASIC *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1112XX;1113XX*[1]

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

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QPS-0535-20**

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:

Nome prodotto *(Product name)*	***Codice*** *(Code)*
EUROPLUS+ *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1141XX; 1147XX*[1]
EURO SCS *Sacche sterili per contenimento liquidi biologici* *(Sacche sterili per contenimento liquidi biologici)*	*1142XX; 1143XX; 1144XX; 1145XX; 1146XX; 1148XX*[1]
D5 *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*1114XX*[1]
EUROBABY *Sacche sterili per contenimento liquidi biologici* *(Sterile bags for collection of body fluids)*	*115100M; 115100F*[1]

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

Istituto Superiore di Sanità

ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no. **QPS-0535-20**

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:

Nome prodotto *(Product name)*	***Codice*** *(Code)*
Sacca sterile raccolta liquidi (Sterile liquid collection bags)	*MS/0005xy*[2]

Il codice di cui sopra ha il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:
[1]*XX:* individua la specifica caratteristica del prodotto
[2]*x*: individua la capacità della sacca; *y*: individua la connessione della sacca (assente o "G"=connettore conico grande, M=connettore conico medio, D=connettore conico piccolo, U=connettore universale per drenaggi, P=Luer lock femmina piccolo, U=universale per drenaggi, LM=Luer lock maschio con tappo)

Valutazione della Conformità: vedi MOD-341-01-01 n. 261/20
Conformity assessment : see MOD-341-01-01 n. 261/20

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

Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° **QPZ-1939-20** Addendum n° //-//
Certificate no. *addendum no.*

Data prima emissione *First issue date*	**16.06.2020**
Data di emissione corrente *Current issue date*	**16.06.2020**
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

CHIMED S.r.l.

***Sede Legale/** Registered Office:*
Via dell'Artigianato, 49 – 57121 Livorno (LI) 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)

*** 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-1939-20**

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)*
Set sterile per aspirazione chirurgica postoperatorio ad alto vuoto *(High-vacuum sterile set for post-operative surgical suction)*	MS/10xy/kkk/zz; MS/105y; MS/10m/jj/zz[1]
Set aspirazione chirurgica postoperatorio a basso vuoto *(Low-vacuum sterile set for post-operative surgical suction)*	MS/11xy/kkk/zz; MS/11mn/p; MS/115q/500; MS/10m/xx/zz[2]
Set aspirazione chirurgica postoperatorio a caduta *(Gravitational sterile set for post-operative surgical suction)*	MS/12x/yy MS/0005wz[3]
Set per toracentesi / paracentesi *(Thoracentesis / paracentesis set)*	MS/3xxy/kkk/zz[4] MS/00055mn
Set per aspirazione chirurgica Yankauer *(Yankauer surgical suction set)*	MS/20x; MS/20xF; MS/2yz/kkk; MS/20x/kkk; MS/20xF/kkk[5]

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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)*
Drenaggi chirurgici ed aspiratori in silicone (Silicone surgical drains and reservoirs)	*MS/00012/xx; MS/00012/50/xx; MS/00013/yy; MS/00014/yy; MS/00015/yy; MS/00040/mis MS/4020/mis; MS/00040A/mis; MS/4020A/mis; MS/00061; MS/00061/40; MS/0008k/xx; MS/00020/xx; MS00041/zzz*[6]
Catetere ureterale di Bracci (Bracci ureteral catheter)	*MS/00075/xx R*[7]

Il codice di cui sopra ha il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

[1]*x*: individua la composizione del sistema (0=solo flacone di ricambio, 1=flacone con tubo di collegamento, 2=flacone con tubo di collegamento e drenaggio, 3=flacone con tubo di collegamento e drenaggio/ago); *y*: individua il tipo di collegamento (L=tubo con attacco Luer al flacone, Y=tubo con connessione per due drenaggi, V=tubo con valvola di non ritorno (possono essere presenti contemporaneamente più specifiche)); *kkk*: individua la capacità del sistema in ml; *zz*: individua la misura del drenaggio in PVC in Charriere; *m*: individua la lunghezza della perforazione del drenaggio e la presenza di ago; *jj*: individua la lunghezza del drenaggio in cm

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

[2]*x*: individua la composizione del sistema (0=solo soffietto di ricambio, 1=soffietto con tubo di collegamento, 2=soffietto con tubo di collegamento e drenaggio, 3=soffietto con tubo di collegamento e drenaggio/ago); *y*: individua il tipo di collegamento (assente=tubo di collegamento per la connessione di un drenaggio, Y=tubo di collegamento per la connessione per due drenaggi); *kkk*: individua la capacità del sistema in ml; *zz*: individua la misura del drenaggio in PVC in Charriere; *m*: individua la composizione del sistema (5=soffietto con sacca di scarico e tubo di collegamento, 6=soffietto con sacca, tubo di collegamento e drenaggio PVC, 7=soffietto con sacca, tubo di collegamento e drenaggio PVC con ago, 8=soffietto con sacca, tubo di collegamento e drenaggio diritti silicone, 9=soffietto con sacca, tubo di collegamento e drenaggio piatto/scanalato in silicone); *n*: individua eventuali caratteristiche del dispositivo (assente=nessuna caratteristica specifica addizionale, V=soffietto dotato di doppia valvola di non ritorno; R=sacca di raccolta dotata di rubinetto, Y=tubo di collegamento datato di connessione di due drenaggi, T=drenaggio piatto in silicone dotato di perforazione per 4/4, A=drenaggio piatto o scanalato dotato di ago); *p*: la misura del drenaggio fornito con il dispositivo (assente=dispositivo fornito senza drenaggio, se presente: misura in Ch del drenaggio rotondo, misura del drenaggio piatto, misura in mm del drenaggio scanalato a sezione rotonda e misura drenaggio scanalato a sezione piatta); *q*: individua la sacca di raccolta (assente=sacca con rubinetto di scarico, V=saccca con filtro aria); *m*: individua la lunghezza della perforazione e la presenza di ago (6=perforazione cm 7, senza ago, 7=perforazione cm 15, senza ago, 8=perforazione cm 7, con ago, 9=perforazione cm 15, con ago); *xx*: individua la lunghezza del drenaggio in cm; *zz*: individua la misura del drenaggio in Cherriere

[3]*x*: individua il tipo di drenaggio e la capacità della sacca (0=drenaggio diritto con sacca da 2000 ml, 1=drenaggio dritto con sacca da 500 ml, 2=drenaggio piatto perforato 3/4 con sacca da 2000 ml, 2T=drenaggio piatto perforato 4/4 con sacca da 2000 ml, 3=drenaggio piatto perforato 3/4 con sacca da 500 ml, 3T=drenaggio piatto perforato 4/4 con sacca da 500 ml, 4=drenaggio a "T" con sacca da 2000 ml, 5=drenaggio a "T" con sacca da 500 ml, 6=drenaggio "Penrose" con sacca da 2000 ml, 7=drenaggio "Penrose" con sacca da 500 ml, 8=drenaggio scanalato con sacca da 2000 ml, 8A=drenaggio scanalato con ago e sacca da 2000 ml, 9=drenaggio scanalato con sacca da 500 ml, 9A=drenaggio scanalato con ago e sacca da 500 ml); *yy*: individua la misura del drenaggio; *w*: individua la capacità della ssacca; *z*: individua la connessione della sacca (assente o "G"=connettore conico grande, M=connettore conico medio, D=connettore conico piccolo, U=connettore universale per drenaggi)

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

[4]*xx*: individua il tipo di ago e di sacca contenuto nel set (00=set contr aghi cannula e sacca da 2000 ml, 01=set con ago di Verres e sacca da 2000 ml, 02=set con tre aghi cannula e sacca da 5000 ml, 03=set con ago di Verres e sacca da 5000 ml, 04=set con tre aghi cannula e sacca da 8000 ml, 05=set con ago di Verres e sacca da 8000 ml, 06=set con cannula e ago interno e sacca da 2000 ml, 07=set con cannula e ago interno e sacca da 5000 ml, 08=set con cannula e ago interno e sacca da 8000 ml, 10=set con ago cannula e sacca da 2000 ml); *y*: individua il tipo di set (assente=set con rubinetto a tre vie, V=set con valvole di non ritorno); *kkk*: se presente, indivia la lunghezza dell'ago; *zz*: individua il diametro dell'ago; *m*: individua per codifica la capacità della sacca; *n*: individua la connessione della sacca (P=connessione per set con rubinetto a tre vie, L=connessione per set con valvole di non ritorno)
[5]*x*: individua il tipo di cannula; *yz*: individuano il tipo (diametro) ed il tipo di connettore conico; *kkk*: individuano la lunghezza del tubo di collegamento
[6]*xx*: individua il diametro o la sezione del drenaggio in mm; *yy*: individua il diametro del drenaggio in Ch(Charriere); *mis*: individua la misura del drenaggio piatto in mm x cm; *k:* indica il tipo di drenaggio scanalato; *zzz*: individua la capacità del reservoir in ml
[7]*xx*: individua la misura del catetere in Cherriere

Valutazione della Conformità: vedi MOD-341-01-01 n. 261/20
Conformity assessment : see MOD-341-01-01 n. 261/20

Il Direttore dell'Organismo Notificato
The Director of Notified Body
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CERTIFICATE

Reg. Number	14218 - M	Valid From	2021-04-14
First issue date	1998-05-21	Last change date	2021-05-05
Valid until	2025-05-21		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

CHIMED S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2021 for the following products/services:

Manufacture and sale of sterile and non-sterile collection, drainage and suction sets, sterile and non-sterile liquid collection bags and sterile medical devices for urological, anaesthetic and related application.

President
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.
The date of issuance of this certificate is the date of first issue by another accredited body.
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
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Certified Sites
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SGQ N° 007A