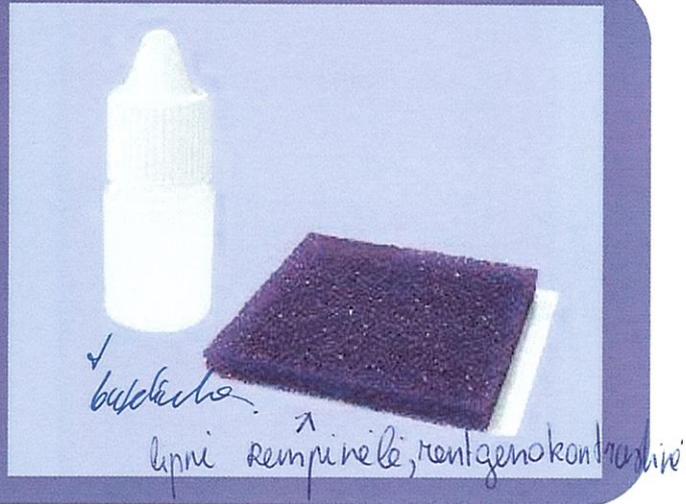


133 power/s

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.

Skilas aparati optika nuo nasojimo

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

Instalacija: 6ml

Skilas pri optiki nasojimo
yo mozkantni u skile

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

Sterily

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.

7 purple surgical



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 *leader*

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

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 16 December 2019 until 15 May 2023
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 31 December 2002
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 207936

This is a multi-site certification.
Additional site details are listed on subsequent pages

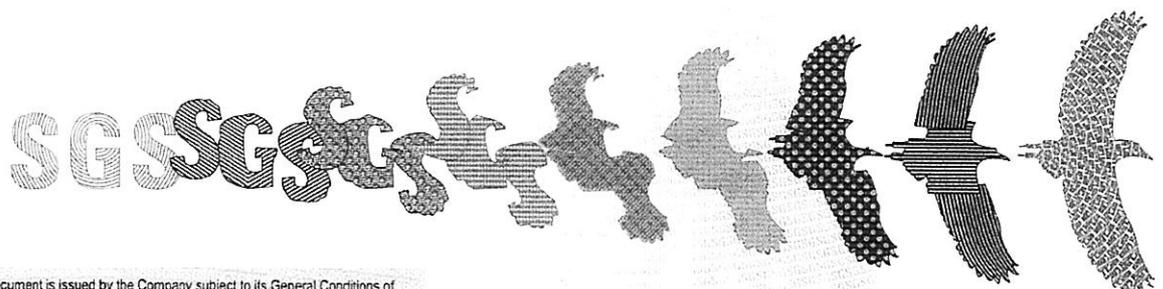
Authorised by

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

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**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 1

Detailed scope

**Sterile pleura sets, 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, Non-sterile irrigation pumps
Sterile and non sterile Veress needles
Sterile and non sterile electro-surgical pencils and electrodes
Sterile and non sterile electro-surgical laparoscopic scissors, graspers & forceps
Sterile and non-sterile laparoscopic electro-surgical electrodes
Sterile surgical staples and staplers.**

**Class I Sterile: Sterility aspects only - Restricted to the aspects of manufacture
concerned with securing and maintaining sterile conditions:
Sterile light handle covers, Sterile eye shields
Sterile ultrasound probe covers, Sterile electro-surgical monopolar Cables
Sterile IUD thread retrievers, Sterile suction tubes & collection sets
Sterile uterine manipulator injectors, Sterile laparoscopic camera sleeve
Sterile skin markers, Sterile endometrial samplers
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