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ESSENTIAL LIGHT HANDLE COVERS

STERILE SUPPLY
PRODUCT DATA SHEET

LEGAL MANUFACTURER:

Shanghai Everpure Medical Plastics Co., Ltd

No. 2418 Tingfeng Rd., Xinnong Town, Jinshan District, Shanghai 201503, China

DISTRIBUTOR:

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

EU REPRESENTATIVE:

CMC Medical Devices & Drugs S.L

C/Horacio Lengo Nº 18 CP 29006, Málaga, Spain

NOTIFIED BODY:

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

DEVICE CLASSIFICATION:

The device is classified as Class I (Sterile) according to Directive 93/42/EEC on Medical Devices (MDD) Annex IX.

GMDN:

GMDN Number: 44977
GMDN Term: Medical Equipment Handle Cover, Single-Use

BASIC UDI:

Single: 05051223037620 (Pouch) - 35051223037621 (Box)
Double: 05051223037606 (Pouch) - 35051223037607 (Box)

DEVICE CONFORMITY:

European Union CE 0197

QUALITY MANAGEMENT SYSTEM:

Shanghai Everpure Medical Plastics Co., Ltd is committed to compliance with & maintaining the effectiveness of the requirements outlined in:

- ISO 13485 Quality Managements System standards
- 93/42/EEC Medical Device Directive
- European Union Medical Device Regulation (MDR): (EU) 2017/745 and Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478)

INTENDED PURPOSE:

The Light Handle Cover is a plastic cover intended to prevent direct contact with the surgical light handle when the doctor adjusts the position of the light, to avoid causing cross contamination.

ASSOCIATED MODELS:

PRODUCT CODE:	MODEL DETAILS:
PS4611A	Essential Light Handle Cover – Single Pack
PS4612A	Essential Light Handle Cover – Dual Pack

TECHNICAL SPECIFICATIONS:

The Essential Light Handle Cover is a single use device and is supplied sterile.

The Essential Light Handle Cover is durable, light and a snug fit to the Purple Surgical or similar light handle fixtures.

REQUIRED ACCESSORIES TO BE USED WITH OR IN COMBINATION WITH THE DEVICE:

The Essential Light Handle Cover has been designed to be used with the most common shape of operating lighting system handle grips.

MATERIAL DATA:

COMPONENT	APPEARANCE	MATERIAL / GRADE	CAS NO
Light Handle Cover	Purple	PE	-

IDENTIFICATION OF MATERIALS WITH DIRECT AND/OR INDIRECT CONTACT WITH THE BODY:

The patient is not directly exposed to the Light Handle Cover during intended use.

The device will be intermittently held by the gloved hands of the healthcare professional user.

BIOLOGICAL EVALUATION:

In accordance with ISO 10993-1 / EN ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-23.

REACH:

The substances, which are contained in the Device, and require registration under REACH, have been (pre-) registered by our upstream suppliers. Substances, listed in Annex XVII of the EU Regulation No 1907/2006, concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), are not intentionally used or added in the formulation of the Device. However, since the product has not been tested for these substances, we cannot guarantee that there is no trace amount present, as impurity or otherwise.

The Device does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) in a concentration above the threshold limit of 0.1 % (w/w) as stated in the REACH (Article 57).

The Device does not contain any of the biocides as stated in the EU Regulation No 528/2012 concerning biocidal products.

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

PFAS:

Per- and polyfluoroalkyl substances (PFAS) is a group of substances widely used in many industries. Due to growing awareness of health and environmental concerns, PFAS are facing increasing scrutiny worldwide. In-force and proposed measures set restrictions or requirements on PFAS use in some jurisdictions, and due diligence may be necessary to meet legal obligations, ESG commitments, and/or business requirements.

Based on the available documentation from raw materials suppliers, however, the products supplied by Purple Surgical have been evaluated to the PFAS list, and have been found not to contain any of the chemicals above the defined threshold, listed in the PFAS Substance List.

The substances are not intentionally used or added in the formulation of the supplied products. However, since the products have not been tested for these substances, we cannot guarantee that there is no trace amount present, as impurity or otherwise.

TSCA:

The U.S. Toxic Substances Control Act of 1976 (TSCA) addresses the production, importation, use, and disposal of certain chemicals into or within the United States, and provides the U.S. Environmental Protection Agency (EPA) with the authority to require reporting, record-keeping, and restrictions relating to chemical substances and/or mixtures.

Based on the available documentation from raw materials suppliers, however, the products supplied by Purple Surgical have been evaluated to the TSCA list, and have been found not to contain any of the chemicals above the defined threshold, listed in the TSCA Substance List, covered by the Act.

The substances are not intentionally used or added in the formulation of the supplied products. However, since the products have not been tested for these substances, we cannot guarantee that there is no trace amount present, as impurity or otherwise.

MANUFACTURING ENVIRONMENT:

Products are packed in a cleanroom environment which is validated and monitored in accordance with ISO 14644-1, ISO 14644-2 and ISO 14644-3.

BIOBURDEN TESTING:

The bioburden of this product, after the manufacturing and cleaning process, is routinely monitored in compliance with ISO 11737-1. This gives assurances to the compliance with ISO 11737-2 for sterility aspects.

STERILISATION REQUIREMENTS:

Are the devices supplied sterile?	Yes
Sterilisation Method	Ethylene Oxide
Shelf Life	3 Years
Is sterilisation required prior to use?	No
Supplied for user sterilisation?	No
Supplied to Virtual Manufacturer for sterilisation?	No

INFORMATION SUPPLIED BY THE MANUFACTURER:

Labelling:	In accordance with BS EN ISO 20417 and BS EN ISO 15223-1
Instructions For Use (DOC 229):	As is required by Medical Device Regulation – EU Regulation 2017/745 (MDR), Annex I "General Safety and Performance Requirements", Chapter III "Requirements regarding the information supplied with the device"

PACKAGING:

Unit Packaging Grid Lacquer Medical Craft Paper with Nylon Film

Box Packaging	Shelf Box		Shipping Carton			
Product Code	**Qty (pcs)**	**Dimensions (mm) (L x W x D)**	**Qty (pcs)**	**Dimensions (mm) (L x W x D)**	**Unit Weight (g)**	**Gross Weight (Kg)**
PS4611A	100	600 x 400 x 400	-	-	12.50	1.5
PS4612A	100	580 x 400 x 520	-	-	16.80	2

STORAGE AND HANDLING:

SINGLE-USE WARNING:

DISPOSAL:

This product is to be disposed of as controlled medical waste according to national guidelines.

AMENDMENTS LOG

Issue / Reason for Change	Date	Approved By
Issue 1 / First Issue	08.05.2025	P. Betty

Note: Information within this datasheet has been compiled by Purple Surgical from information provided by the legal manufacturer.