



EC DECLARATION OF CONFORMITY

Purple Surgical Holdings Limited (PSH)

Also known as:

- Purple Surgical International Limited (PSI)
- Purple Surgical UK Limited (PSUK)
- Purple Surgical Manufacturing Limited (PSM)

2 Chestnut House

Farm Close

Shenley

Herts

WD7 9AD

England

Device Description: Light Handle Covers – Sterile supply

Intended Use: The Light Handle Cover is used in theatres to cover the light handle, allowing control of movement & focusing of the light by the surgeon, and preventing cross contamination to the patient.

Part Code(s):

- PS4611
- PS4612
- 89-940-20-04

GMDN Code: 44977

GMDN Term: *Operating\Examination\Treatment light handle cover, single use*

Declares the medical device(s) described above are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC, as amended by Directive 2007/47/EC
The Device(s) are classified as **Class: 1 sterile, Rule: 1**, and are subject to the procedure set out in ***Annex II (sterility aspects only)** of the Directive under the supervision of

Notified Body 1639
SGS Belgium NV
Noorderlaan 87
BE-2030 Antwerpen
Belgium

Authorised EU Representative
Advena Limited
Tower Business Centre
2nd Floor
Tower Street
Swatar BKR 4013
Malta

*Certificate Ref: GB19/964712.

For and on behalf of the company

A handwritten signature in blue ink, appearing to read "Elaine Gudge".

Elaine Gudge
RA Specialist

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

| Standard/Document Name | Description |
|------------------------|---|
| 93/42/EEC | Council Directive concerning medical devices as amended by Directive 2007/47/EC |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2019 | Medical Devices – Application of Risk Management to Medical Devices |
| BS EN ISO 15223-1:2016 | Terminology, symbols for use and information to be supplied with medical devices. |