

## EC DECLARATION OF CONFORMITY

### Purple Surgical Holdings Limited

Also known as:

- Purple Surgical International Limited
- Purple Surgical UK Limited
- Purple Surgical Manufacturing Limited

2 Chestnut House

Farm Close

Shenley

Herts

WD7 9AD

England

**Device Description: Light Handle Covers – Sterile supply**

### Part Code(s):

- PS4611
- PS4612
- PS4613
- PS4611S
- PS4612S
- 89-940-20-04
- BUHC100X1

**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 V (sterility aspects only)** of the Directive under the supervision of

**Notified Body 0120**

**SGS United Kingdom Ltd**

**Unit 202B Worle Parkway**

**Weston Super Mare BS22 6WA United Kingdom**

For and on behalf of the company



Jason Howes  
RA Manager