



## 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:** *Vessel loops*

### Part Code(s):

- *PS3001*
- *PS3002*
- *PS3003*
- *PS3004*
- *PS3201*
- *PS3202*
- *PS3203*
- *PS3204*

**GMDN Code:** **61916**

**GMDN Term:** **Surgical Vessel Loop**

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: IIA, Rule: 6**, and are subject to the procedure set out in **\*Annex II (excluding section 4)** of the Directive under the supervision of:

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

**Authorised EU Representative**  
**Advena**  
**Tower Business Centre**  
**2<sup>nd</sup> Floor**  
**Tower Street**  
**Swatar BKR 4013**  
**Malta**

\*Certificate Ref: GB19/964712.

For and on behalf of the company

A blue ink signature of C. Walters, written in a cursive style, on a light blue rectangular background.

C. Walters  
RA Specialist

Revision No: 8

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