



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: *Surgical Skin markers – sterile supply*

Part Code(s):

- *PS3150*
- *PS3150NR*
- *PS3150L*
- *PS3151*
- *PS3158*
- *PS3158L*

GMDN Code: *61575*

GMDN Term: *Skin Marker pen, single use, sterile*

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

Tower Business Centre

2nd 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, is placed over a light blue rectangular background.

C.Walters

RA Specialist

Revision No: 9

Revision Date: 21/04/2020

Supersedes 01/04/2020