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## **SPECIFICATION**

### **PSDS Opsite IV3000 1 Hand**

#### Approvals

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# SPECIFICATION

## PSDS Opsite IV3000 1 Hand

### SPECIFICATION

#### 1. PRODUCT NAME(S):

OPSITE IV 3000 1-HAND

#### 2. INTENDED USES:

For the fixation of intravenous catheters.

#### 3. COMPOSITION:

**Strips and Label Format:** - Hydrophilic Polyurethane film supported by a release coated carrier film and coated with an adhesive. A siliconised release handle is located on the adhesive layer at one end of the dressing. On the adhesive layer at the opposite end of the dressing is a double sided siliconised release handle containing three non-woven strips, spread with a cellulose adhesive. One of the strips is printed with black ink, providing the required symbols for the documentation label. A release coated paper covers over and protects the handles and the remaining adhesive area.

For ported products at the port side there is non-woven material coated with adhesive.

**Non-Strips and Label Format:** - Hydrophilic Polyurethane film supported by a release coated carrier film and coated with an adhesive. A siliconised release handle is located on the adhesive layer at one end of the dressing. A release coated paper covers over and protects the handle and the remaining adhesive area.

For ported products at the port side there is non-woven material coated with adhesive.

#### 4: PHYSICAL AND CHEMICAL PROPERTIES:

Combustible solid.

#### 5. HAZARD INFORMATION:

**Health Effects:** No health hazard is anticipated during normal handling of this product.

#### 6. FIRST AID:

- a) **Inhalation** - Not applicable.
- b) **Contact with skin** - Not applicable.
- c) **Contact with eyes** - Not applicable.
- d) **Ingestion** - Not applicable.

#### 7. FIRE AND EMERGENCY MEASURES:

The product is a combustible solid which gives off toxic fumes, mainly carbon monoxide, carbon dioxide and hydrogen cyanide, when ignited. In case of fire any standard fire extinguisher may be used; wear self-contained breathing apparatus.

#### 8. ACCIDENTAL RELEASE MEASURES:

Not Applicable

#### 9. HANDLING AND STORAGE PRECAUTIONS:

Store in a cool, dry place. Keep away from sources of ignition.

#### 10. EXPOSURE CONTROLS/PERSONAL PROTECTION:

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Not Applicable.

**11. STABILITY AND REACTIVITY:**

Not Applicable.

**12. TOXICOLOGICAL INFORMATION:**

See information given in Hazard Information: Health Effects.

**13. ECOLOGICAL INFORMATION:**

Not Applicable.

**14. DISPOSAL:**

Controlled incineration/landfill according to local environmental health guidelines.

**15. TRANSPORT PRECAUTIONS:**

See Handling and Storage Precautions.

**16. REGULATORY INFORMATION:**

Not applicable.

**17. ADDITIONAL INFORMATION:**

Not applicable.

**18. NAME, ADDRESS AND TELEPHONE NUMBER OF SUPPLIER:**

Documentation and Records Department  
Smith & Nephew Medical Limited  
PO Box 81  
Hessle Road  
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This information is provided in accordance with the requirements of the UK Health and Safety at Work Act 1974, and specifically in order to assist users of the product to make their 'assessment of health risks' as required by the UK Control of Substances Hazardous to Health Regulation 2002 (COSHH assessments). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides.

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

**REASON FOR CHANGE**

| Document Version | Section/Paragraph Changed | Change Made   | Date     |
|------------------|---------------------------|---|----------|
| 2                | Product Code List         | Removal of Product codes 66604009 & 66694009. Codes discontinued.   | 04/01/07 |
| 3                | 3                         | Clarification of composition details for 'strips and label' and 'non-strips and label' format according to CCA/820 and CCA/987. | 07/02/07 |
| 4                | 3 and Product Code List.  | Additional information added for the non-woven port section of the dressing. Addition of product codes 66394011 and 66004011    | 12/03/07 |
| 05               | N/A                       | Periodic review – No change   | 19/07/12 |

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Plant Number(s):

None

Product Code(s):

4007, 4008, 4016, 4018, 4654, 59410082, 59410400, 59410882, 59411200, 66004011  
66024007, 66024008, 66024018, 66024654, 66394007, 66394008, 66394011, 66394654  
66604006, 66604007, 66604008, 66694006, 66694007, 66694008, 66800421, 66800422

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