

e-PRODUCT INFORMATION FORM

Please complete and forward electronically to Clinical Product Co-ordinator (CPC) within a PEHNZ affiliated Health Care provider. Supplier will be contacted prior to further promotion

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| Date: | 09 JAN 2013 |
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| Product Line: CERVICAL SPINAL TRACTION DEVICE (e.g. Urine Catheters) | Code: <i>(If more than 1 please list separately)</i> | List Price: \$35,000 |
| Description: This device is a prototype developed for the treatment of low impact cervical spine dislocations, and will be delivered as a calibrated unit pre-assembled with a modified Howard Wright M7 Trauma Stretcher. | | |

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| Manufacturer/Brand Name: OSSIS LTD | Country of Manufacture: NEW ZEALAND |
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SUPPLIER DETAILS:

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| Agent: OSSIS LTD | Distributor: - | Manufacturer: - |
| Company Address: PO Box 6047, Upper Riccarton, Christchurch | | |
| Representative Name: DAVE BODY | Signature:(if requested) | |
| Email: davebody@windowslive.com | Phones – Mobile/Office: +64 (21) 778 908 +64 (03) 365 7369 | |

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| Is product new to New Zealand? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Does the product or packaging contain Latex or DEHP? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> | If Yes , please tick which Latex <input type="checkbox"/> DEHP <input type="checkbox"/> |
| Is this a reusable or single use item? | Reusable <input checked="" type="checkbox"/> | Single <input type="checkbox"/> Single patient <input type="checkbox"/> |
| Is the product supplied clinically clean or sterile? | Clean <input checked="" type="checkbox"/> | Sterile <input type="checkbox"/> |
| Expected shelf life at manufacture: | Years: NA | Months: |
| Is this product or any of its components derived from human or animal tissue? (Further clarification may be requested) | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

COPY OF ALL RELEVANT COMPLIANCE AND REGULATORY CERTS MUST BE PROVIDED (electronically)

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| WAND listing | Yes <input checked="" type="checkbox"/> | No. 130108-WAND-6EPELN Copy Supplied | No <input type="checkbox"/> Exemption classification |
| Certification Type: CE | No. | Copy supplied | |
| Certification Type: FDA | No. | Copy supplied | |

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| Certification Type: TGA | No. | Copy supplied |
| ISO | 13485 | Copy supplied ATTACHED |
| GMP | NA | Copy supplied |
| Sterilisation compliance | NA | Copy supplied |
| Letter of conformity | TO BE SUPPLIED AFTER EVALUATION | Copy supplied |
| Material Safety Data Sheet | NA | Copy supplied |
| Any other supporting compliance data eg NZS, AS/NZS, IEC, EEC | | |
| Is this product in use in other hospitals in New Zealand/Australia? | Yes <input checked="" type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Example of sites: WAIKATO HOSPITAL | | |

Supporting Product Related Information:

Comments: NA

Health and safety:

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| Does the product or packaging contain any Hazardous Substances? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Does the product or packaging contain Sharps? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Are there any Manual Handling issues? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Are there any safety precautions or contra-indications in regard to the use of this product? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| If yes to any of above, please describe: The weight of the device (including the bed) will exceed 150kg. Dr. Raj Singhal will provide information on the safe use and contra-indications of the device. | | |

Training:

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| Will your company be providing Training for this product? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| If yes, please describe what this will include: Dr. Raj Singhal will provide on-site training, as well as operation manuals and videos. | | |

Biomedical Equipment:

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| Is the device able to be serviced on site? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Is there a dedicated NZ service agent for the product/range? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Do you supply Biomedical training? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Are service manuals and technical specifications provided? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| TESTED for essential safety and performance parameters in accordance with AS/NZS3551 (Certificates may be requested) | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Service can be performed by in-house biomed staff | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |