Product Code (please leave blank)

PRODUCT DATASHEET

With this form the following must be attached where applicable:

- Sample(s) of the product
- Brochures of the product
- Occupational Health and Safety considerations
- Infection Control considerations
- Written operating procedures and/or instruction for use
- Business card of company representative

Note: No product will be considered for evaluation/trial unless it is accompanied by this form.

New Zealand Supplier:			
Agent/Distributor/Manufacturer:			
Address:			
Telephone:		**Fax:**	
Email:			
Representative Name:			
Representative Telephone & Email:			

I have read and understand all the terms in the ***Trial of Equipment*** (ToE) document and agree to the terms and conditions described. Signing this document, the Product Datasheet, invokes the terms and conditions of the ToE document even if the ToE document remains unsigned.

I guarantee that I have taken all steps necessary to ensure that the information contained in this form is true, correct and not misleading.

Signed: …… Date: …….

Print Name: ……..

Designation: ……..

Company: ……..

Product Name:	
Manufacturer/Brand Name:	
Product Code:	
Item/Catalogue Number:	
Country of Manufacturer:	
FDA/TGA/CE Marking Standards Number:	
NZ/Australian Standards Title/Name and Number:	
ECRI Code: *(Please attach copies of certification)*	
List Price:	
Minimum Order Quantity:	
Standard Packaging:	
Does this product contain latex?	
Does the packaging contain latex?	
Is this a new product/replacement product or upgrade of an existing product?	
If replacement or up-grade, what product is it replacing?	
Reason for evaluation:	
Can inservice be provided by your company?	
Is this a single use or re-usable item? *(If reusable item, please attach information regarding sterilisation of the product)*	
Are instructions for use in English?	
Expected shelf life:	
Is the product currently in use in other DHB's? Yes o No o *(please tick)* *(If yes, state whether the product is used throughout the organisation or in which single area/dept)*	

If this product is sterile, please provide evidence of satisfactory sterilisation (e.g. a GMP certificate) and the standards met in the storage and transport of the product from factory to the hospital.

Copies of certificates relating to product standards must be attached.
All certification must be supplied before the product will be accepted for assessment for suitability

Key:	FDA	=	Food and Drug Administration *(USA)*	ECRI	=	Emergency Care Research Institute *(USA, UK & Malaysia)*
	TGA	=	Therapeutic Goods Administration *(Australia)*			
	CE Marking	=	Conformite Europeene *(Europe)*			

CAPITAL EXPENDITURE ITEMS ONLY

(For detail, please explain on separate pages and attach to this form)

Can you supply 2 or more operator manuals: *(If "No" please explain)*	
Can you supply 1 or more service manuals which include the following: ▪ **Operating instructions** ▪ **Complete schematic diagrams** ▪ **Circuit description** ▪ **Troubleshooting procedures** ▪ **Functional testing procedures** ▪ **Calibration procedures** ▪ **Replacement parts list, electrical** ▪ **Replacement parts list, mechanical** **(If "No" please explain)**	
Can you supply operating personnel training sessions, and who will be providing this training?	
Can you supply biomedical training? *(Please provide details i.e. who, where, what level, possible cost etc)*	
Can you provide a replacement unit during servicing?	
What is the warranty period in months for both parts and labour?	
How will you support post warranty repair by the purchaser?	
Do you have a circuit board exchange policy?	
Can repair parts be purchased direct from the manufacturer?	
Does this product require special biomedical equipment for calibration/repair? *(Please provide details)*	
If this product requires consumables, please state which consumables may be used under warranty and beyond warranty: *Please fill in the first part of this form for any consumables required*	