

TGA THERAPEUTIC GOODS ADMINISTRATION
CONFORMITY ASSESSMENT BRANCH



IPU APPLICATION FORM

Mail: The clinical section, Conformity Assessment Branch, PO Box 100, Woden ACT 2606
Fax: The clinical section, Conformity Assessment Branch (02) 6232 8785

Device

Name: PIP
 Model: CONEIVE CER SILICONE IMPLANTS ROUND HIGH PROFILE
 Size: 35000
 Quantity: 2

Supplier Name: PRECISE MEDICAL
 Address: P.O. Box 421 PADDINGTON 2021
 Phone: 9211 8411
 Fax: 9211 8271

Clinical Justification for using an unapproved device

Androulencous mastectomy and silicone implants 17 yrs ago Possible rupture (L) implant - requires replacement of both implants - unsufficient skin cover for valve prostheses

(Where a currently approved device is available, indicate the advantages of the requested device)

Patient

Initials:
 Date of birth: 14.3.40

Procedure

Proposed date: 23 5.01
 Institution: NORTH COAST PRIVATE HOSPITAL

Doctor

Name:
 Address:
 Phone:
 Fax:

Signature: *[Signature]*

Appro *[Stamp]*

Please use proforma or replica thereof on your wordprocessor.
All enquiries should be directed to the administrative officer on phone (02) 6232 8679