

Extract from *IVD Applications Summary Workbook v.20101201.xlsx*

Application ID	Submission ID	Sponsor	Manufacturer	Class	GMDN	Application Fees Paid	20 Day Decision Date	Assessor assigned	Decision	Date of decision	Date of notification	ARTG number
DV-2013-IVA-01148-1	DA-2013-00614-1	Immuno Pty Ltd	Mardx Diagnostics Inc (USA)	2	CT353 Bacterial infectious disease IVDs	30/01/2013		s.2	Approved	4/02/2013	4/02/2013	205544

Office of Devices Authorisation Delegate's Checklist

Note: This form must be completed for each individual decision of the Delegate and placed on the relevant file.

For use by Delegates with delegated authority
on behalf of the Minister or Secretary under:
Therapeutic Goods Act 1989 (Act)
Therapeutic Goods Regulations 1990 (Regs)
Therapeutic Goods (Medical Devices) Regulations 2002 (Device Regs)

Name of Recipient (to whom this decision relates): Immuno Pty Ltd

Company/business name (where relevant):

Submission/ARTG Number (where relevant): DA-2013-00614-1
ARTG 205544

1. Are you making this decision under the Act, Regs or Device Regs? (tick one)	Act <input checked="" type="checkbox"/> Regs <input type="checkbox"/> Device Regs <input type="checkbox"/>
2. Under which Section or Regulation are you making this decision?	s41FF
3. Do you have a current delegation under that Section or Regulation?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
4. Have you checked that all aspects and/or requirements of that Section/Regulation have been considered or met in making this decision?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

Delegate's Name:	s.22
Position Number:	
Signature:	
Date:	4 February 2013