

# IVD pricing schedule

<b>Conformity Assessment All Procedures</b>	<b>Fee \$</b>
Application for Conformity Assessment Certificate - All Procedures	790
<b>Conformity Assessment - Initial Assessment</b>	<b>Fee \$</b>
Schedule 3, Part 1 - Full Quality Management System Audit	23,900
Schedule 3, clause 1.6 - Design Examination	51,000
Schedule 3, clause 1.6 - Design Examination (immunohaematology reagent)	12,500
Schedule 3, clause 1.6 - Design Examination (abridged)	3,010
Schedule 3, Part 2 - Type Examination	33,000
Schedule 3, Part 4 - Production Quality Management System Audit	21,000
<b>Conformity Assessment Surveillance Audits</b>	<b>Fee \$</b>
Schedule 3, Part 1 - Full Quality Management System Surveillance Audit	6,970
Schedule 3, Part 4 - Production Quality Management System Surveillance Audit	6,970
<b>Inclusion in the ARTG - Application for an inclusion in the Register</b>	<b>Fee \$</b>
Class 1 IVD medical device	810
Class 2 IVD medical device	810
Class 3 IVD medical device	810
Class 4 IVD medical device	810
Class 4 In-house IVD medical device	810
<b>Inclusion in the ARTG - Application Audit Assessment (Technical File Review)</b>	<b>Fee \$</b>
Mandatory	5,500
Non-mandatory	0
<b>IVD Medical Devices - Annual Charges (until 30/06/2013)</b>	<b>Fee \$</b>
Class 1 IVD medical device	0
Class 2 IVD medical device	0
Class 3 IVD medical device	0
Class 4 IVD medical device	0
Class 4 In-house IVD medical device	0
<b>In-house IVD Medical Devices</b>	<b>Fee \$</b>
Class 1-3 In-house IVD medical device notification charges	810