

Impact of changes to the LVT exemption scheme on charges for medical devices companies

	Charges under the current Scheme								Charges under the proposed scheme					
	Rate	Total entries	LVT - zero turnover	LVT - low turnover	Net entries	Annual charges	LVT Application fees	Total paid	Rate reduced by	New Rate	LVT - zero turnover	Net entries	Annual charges	Impact
	\$	#	#	#	#	\$	\$	\$	%	\$	#	#	\$	\$
VOCO Australia Pty Ltd														
Device Class AIMD	1,180								5%	1,121				0
Device Class III	1,180								5%	1,121				0
Device Class IIb	920								5%	874				0
Device Class IIa	920	30	3	23	4	3,680	4,030	7,710	5%	874	3	27	23,598	(15,888)
Device Class I Sterile	600								0%	600				0
Device Class I Measuring	600								0%	600				0
Device Class I 'Other'	80	14	0	0	14	1,120		1,120	0%	80		14	1,120	0
Listed Devices	1,320								0%	1,320				0
Listed Devices - IVD, Tampons & Disinfectants	750								0%	750				0
Registered Devices - IVD, Tampons & Disinfectants	1,480								0%	1,480				0
Total		44	3	-	-	-	-	-					-	0
Dentsply (Australia) Pty Ltd														
Device Class AIMD	1,180								5%	1,121				0
Device Class III	1,180								5%	1,121				0
Device Class IIb	920	1			1	920		920	5%	874		1	874	46
Device Class IIa	920	91	13	21	57	52,440	5,270	57,710	5%	874	13	78	68,172	(10,462)
Device Class I Sterile	600	2		1	1	600	155	755	0%	600		2	1,200	(445)
Device Class I Measuring	600	2			2	1,200		1,200	0%	600		2	1,200	0
Device Class I 'Other'	80	163			163	13,040		13,040	0%	80		163	13,040	0
Listed Devices	1,320								0%	1,320				0
Listed Devices - IVD, Tampons & Disinfectants	750								0%	750				0
Registered Devices - IVD, Tampons & Disinfectants	1,480								0%	1,480				0
Total		259	13	-	-	-	-	-					-	0
City Dental Supplies (T/a Casemate)														
Device Class AIMD	1,180								5%	1,121				0
Device Class III	1,180								5%	1,121				0
Device Class IIb	920								5%	874				0
Device Class IIa	920	6	0	3	3	2,760	465	3,225	5%	874		6	5,244	(2,019)
Device Class I Sterile	600								0%	600				0
Device Class I Measuring	600								0%	600				0
Device Class I 'Other'	80	10	0	0	10	800		800	0%	80		10	800	0
Listed Devices	1,320								0%	1,320				0
Listed Devices - IVD, Tampons & Disinfectants	750								0%	750				0
Registered Devices - IVD, Tampons & Disinfectants	1,480								0%	1,480				0
Total		16	-	-	-	-	-	-					-	0
Amalgadent Dental Supplies (Australan) Pty Ltd														
Device Class AIMD	1,180								5%	1,121				0
Device Class III	1,180								5%	1,121				0
Device Class IIb	920						155	155	5%	874			874	(739)
Device Class IIa	920	28	1	10	17	15,640	1,705	17,345	5%	874	1	77	23,598	(6,253)
Device Class I Sterile	600								0%	600				0
Device Class I Measuring	600								0%	600				0
Device Class I 'Other'	80	100			100	8,000		8,000	0%	80		100	8,000	0
Listed Devices	1,320								0%	1,320				0
Listed Devices - IVD, Tampons & Disinfectants	750				1	750		750	0%	750		1	750	0
Registered Devices - IVD, Tampons & Disinfectants	1,480								0%	1,480				0
Total		130	1	-	1	750	-	750				1	750	0
J Wisbey & Assoc Pty Ltd														
Device Class AIMD	1,180								5%	1,121				0
Device Class III	1,180								5%	1,121				0
Device Class IIb	920								5%	874				0
Device Class IIa	920	11	4	4	3	2,760	1,240	4,000	5%	874	4	7	6,118	(2,118)
Device Class I Sterile	600								0%	600				0
Device Class I Measuring	600								0%	600				0
Device Class I 'Other'	80	24	0	0	24	1,920		1,920	0%	80		24	1,920	0
Listed Devices	1,320								0%	1,320				0
Listed Devices - IVD, Tampons & Disinfectants	750								0%	750				0
Registered Devices - IVD, Tampons & Disinfectants	1,480								0%	1,480				0
Total		35	4	-	-	-	-	-					-	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications (except for VOCO who did not apply for LVT in 2014-15 - for the purpose of the impact statement 2013-14 data was used);

If an entry has turnover of greater than \$0, the entry will no longer be eligible for exemption under the proposed scheme

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme

Notes to the spreadsheet

Annual charges for AIMD, class III, class IIb, and class IIa medical devices are proposed to reduce by 5% for 2015-16

Figures in red means adverse impact on sponsor companies i.e. increase in annual charges

Company Name	Current Charges	Proposed Charges	Impact

	\$0	\$0	\$0
VOCO Australia Pty Ltd	#REF!	#REF!	#REF!
Dentsply (Australia) Pty Ltd	#REF!	#REF!	#REF!
City Dental Supplies (T/a Casemate)	#REF!	#REF!	#REF!
Amalgamart Dental Supplies (Australian) Pty Ltd	#REF!	#REF!	#REF!
J W & Assoc Pty Ltd	#REF!	#REF!	#REF!
Total	#REF!	#REF!	#REF!

Potential impact of the proposed changes to the LVT exemption scheme on VOCO Australia Pty Ltd

Type of good	2014-15 Annual charge (\$)	Entries on ARTG 1 July 2014	Zero turnover entries	Low turnover entries	Net entries paid annual charges	Annual Charges (\$)	LVT application Fees (\$)	Total paid in 2014/15 (\$)	Net entries that would incur annual charges under the proposed scheme	Impact of the proposed scheme if no change in annual charge rate (\$)	Impact of the proposed scheme if 5% reduction charge rate (\$) [Class IIa, IIb, III and AIMD only]
Device Class AIMD	1,180				-	-	-	-	-	0	TBC
Device Class III	1,180				-	-	-	-	-	0	TBC
Device Class IIb	920				-	-	-	-	-	0	TBC
Device Class IIa	920	30	3	23	4	3,680	4,030	7,710	27	(17,130)	TBC
Device Class I Sterile	600				-	-	-	-	-	0	TBC
Device Class I Measuring	600				-	-	-	-	-	0	TBC
Device Class I 'Other'	80	14	0	0	14	1,120	-	1,120	14	0	TBC
Listed Devices	1,320				-	-	-	-	-	0	TBC
Listed Devices - IVD, Tampons & Disinfectants	750				-	-	-	-	-	0	TBC
Registered Devices - IVD, Tampons & Disinfectants	1,480				-	-	-	-	-	0	TBC
Total		-	-	-	-	-	-	-	-	(17,130)	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications;

The modelling recognises if an entry approved for LVT exemption in 2014-15 had \$0 actual turnover in 2013-14.

If an entry has turnover of greater than \$0, the entry will no longer be eligible for exemption under the proposed scheme

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme

Notes to the spreadsheet

No increase or reduction in medical devices annual charges is proposed for 2015-16

Figures in red means adverse impact on sponsor companies i.e. increase in annual charges

Potential impact of the proposed changes to the LVT exemption scheme on Dentsply Ptd Ltd

Type of good	2014-15 Annual charge (£)	Entries on ARTG 1 July 2014	Zero turnover entries	Low turnover entries	Net entries paid annual charges	Annual Charges (£)	LVT application fees (£)	Total paid in 2014/15 (£)	Net entries that would incur annual charges under the proposed scheme	Impact of the proposed scheme if no change in annual charge rate (£)	Impact of the proposed scheme if 5% reduction charge rate (£) [Class Ia, Ib, II and AIMD only]
Device Class AIMD	1,180				-	-	-	-	-	0	TBC
Device Class II	1,180				-	-	-	-	-	0	TBC
Device Class III	920	1			1	920	-	920	1	0	TBC
Device Class IIIa	920	91	18	23	57	52,440	5,270	57,710	78	(14,050)	TBC
Device Class I Sterile	600	2		1	1	600	155	755	2	(445)	TBC
Device Class I Measuring	600	2			2	1,200	-	1,200	2	0	TBC
Device Class I 'Other'	80	163			163	13,040	-	13,040	163	0	TBC
Listed Devices	1,120				-	-	-	-	-	0	TBC
Listed Devices - ND, Tampons & Disinfectants	750				-	-	-	-	-	0	TBC
Registered Devices - IVI, Tampons & Disinfectants	1,480				-	-	-	-	-	0	TBC
Total										(14,095)	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications.

The modelling recognises if an entry approved for LVT exemption in 2014-15 had 50 actual turnover in 2013-14.

If an entry has turnover of greater than 50, the entry will no longer be eligible for exemption under the proposed scheme.

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme.

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme.

Notes to the spreadsheet

No increase or reduction in medical devices annual charges is proposed for 2015-16.

Figures in red means adverse impact on sponsor companies i.e. increase in annual charges.

Potential impact of the proposed changes to the LVT exemption scheme on City Dental Supplies (T/a Casemate)

Type of good	2014-15 Annual charge (£)	Entries on ARTG 1 July 2014	Zero turnover entries	Low turnover entries	Net entries paid annual charges	Annual Charges (£)	LVT application Fees (£)	Total paid in 2014/15 (£)	Net entries that would incur annual charges under the proposed scheme	Impact of the proposed scheme if no change in annual charge rate (£)	Impact of the proposed scheme if 5% reduction charge rate (£) [Class Ia, Ib, II and AMO only]
Device Class AMO	1,180				-	-	-	-	-	0	TBC
Device Class II	1,180				-	-	-	-	-	0	TBC
Device Class Ib	920				-	-	-	-	-	0	TBC
Device Class Ia	920	6	0	3	3	2,760	465	3,225	6	(2,295)	TBC
Device Class I Sterile	600				-	-	-	-	-	0	TBC
Device Class I Measuring	600				-	-	-	-	-	0	TBC
Device Class I 'Other'	80	10	0	0	10	800	-	800	10	0	TBC
Listed Devices	1,320				-	-	-	-	-	0	TBC
Listed Devices - IVD, Tampons & Disinfectants	750				-	-	-	-	-	0	TBC
Registered Devices - IVD, Tampons & Disinfectants	1,480				-	-	-	-	-	0	TBC
Total										(2,295)	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications;

The modelling recognises if an entry approved for LVT exemption in 2014-15 had 50 actual turnover in 2013-14

If an entry has turnover of greater than 50, the entry will no longer be eligible for exemption under the proposed scheme

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme

Notes to the spreadsheet

No increase or reduction in medical devices annual charges is proposed for 2015-16

Figures in red means adverse impact on sponsor companies i.e. increase in annual charges

Potential impact of the proposed changes to the LVT exemption scheme on Amalgamated Dental Supplies

Type of good	2014-15 Annual charge (£)	Entries on ARTG 1 July 2014	Zero turnover entries	Low turnover entries	Net entries paid annual charges	Annual Charges (\$)	LVT application fees (\$)	Total paid in 2014/15 (\$)	Net entries that would incur annual charges under the proposed scheme	Impact of the proposed scheme if no change in annual charge rate (\$)	Impact of the proposed scheme if 5% reduction charge rate (\$) [Class 0a, 0b, 0c and ARMO only]
Device Class ARMO	1,180				-	-	-	-	-	0	TBC
Device Class 0a	1,180				-	-	-	-	-	0	TBC
Device Class 0b	920	1		1	-	-	155	155	1	(765)	TBC
Device Class 0c	920	28	1	10	17	15,640	1,705	17,345	27	(7,495)	TBC
Device Class 1 Sterile	600				-	-	-	-	-	0	TBC
Device Class 1 Measuring	600				-	-	-	-	-	0	TBC
Device Class 1 'Other'	80	100			100	8,000	-	8,000	100	0	TBC
Listed Devices	1,120				-	-	-	-	-	0	TBC
Listed Devices - IVD, Tampons & Disinfectants	750	1			1	750	-	750	1	0	TBC
Registered Devices - IVD, Tampons & Disinfectants	1,480				-	-	-	-	-	0	TBC
Total		1	-	-	1	750	-	750	1	(8,260)	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications;

The modelling recognises if an entry approved for LVT exemption in 2014-15 had 50 actual turnover in 2013-14.

If an entry has turnover of greater than 50, the entry will no longer be eligible for exemption under the proposed scheme.

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme.

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme.

Notes to the spreadsheet

No increase or reduction in medical devices annual charges is proposed for 2015-16.

Figures in red means adverse impact on sponsor companies, i.e. increase in annual charges.

Potential impact of the proposed changes to the LVT exemption scheme on H Wisbey & Associates Pty Ltd

Type of good	2014-15 Annual charge (\$)	Entries on ARTG 1 July 2014	Zero turnover entries	Low turnover entries	Net entries paid annual charges	Annual Charges (\$)	LVT application fees (\$)	Total paid in 2014/15 (\$)	Net entries that would incur annual charges under the proposed scheme	Impact of the proposed scheme if no change in annual charge rate (\$)	Impact of the proposed scheme if 5% reduction charge rate (\$) [Class Ia, Ib, II and AMO only]
Device Class AMO	1,180				-	-	-	-	-	0	TBC
Device Class III	1,180				-	-	-	-	-	0	TBC
Device Class IIb	920				-	-	-	-	-	0	TBC
Device Class IIa	920	11	4	4	3	2,760	1,240	4,000	7	(2,440)	TBC
Device Class I Sterile	600				-	-	-	-	-	0	TBC
Device Class I Measuring	600				-	-	-	-	-	0	TBC
Device Class I 'Other'	80	24	0	0	24	1,920	-	1,920	24	0	TBC
Listed Devices	1,320				-	-	-	-	-	0	TBC
Listed Devices - IVD, Tampon & Disinfectants	750				-	-	-	-	-	0	TBC
Registered Devices - IVD, Tampon & Disinfectants	1,480				-	-	-	-	-	0	TBC
Total										(2,440)	0

Assumptions

The modelling is based on 2014-15 new and existing entry LVT applications:

The modelling recognises if an entry approved for LVT exemption in 2014-15 had \$0 actual turnover in 2013-14.

If an entry has turnover of greater than \$0, the entry will no longer be eligible for exemption under the proposed scheme.

The number of goods which will be cancelled by sponsors because they would not qualify for exemption under the proposed scheme has not been estimated. It is expected that some products will be cancelled (and that this will vary across product classes) and this will reduce annual charges to the sponsor.

No application fee is proposed under the proposed scheme.

The modelling does not take into account any waivers that may be granted for essential products under a waiver scheme.

Notes to the spreadsheet

No increase or reduction in medical devices annual charges is proposed for 2015-16.

Figures in red means adverse impact on sponsor companies i.e. increase in annual charges.