

Manufacturing Session

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MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY

Manufacturing Session

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- Shelley Tang – TGA
- Mike Flood – TGA
- Derek Fitzgerald – Medsafe
- Trevor Nisbet - Medsafe

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Single Agency

- Companies manufacturing devices above Class I will be audited by the Agency
- Companies producing procedure packs, sterilizing products and re-labelling devices are considered manufacturers.

Manufacturing Session

- This session is for companies manufacturing medical devices in New Zealand
- Currently have 60 New Zealand manufacturers
 - Class I - 48 companies
 - Class I sterile –5 companies
 - Class I Measuring-
 - Class II a - 15 companies
 - Class IIb – 9 companies
 - Class III – 1 company

Information on the WAND database

| | 6 Jan 05 | 16 Oct 05 |
|--------------------------------|----------|-------------------|
| Total number of sponsors: | 229 | 316 |
| Total number of notifications: | 14,218 | 17,857 |
| AIMD | 197 | 222 |
| Class III | 953 | 1,261 |
| Class IIb | 1,801 | 2,346 |
| Class IIa | 3,961 | 4,962 |
| Class I Sterile | 752 | 1,012 |
| Class I Measurement | 260 | 301 |
| Class I | 6,294 | 7,789 |
| Manufacturer's Evidence | | 2052 Certificates |

Information on WAND

- AIMD – total 222
 - Number cloned from DEAL 70
 - Number with EC certificate 130
 - No conformity assessment evidence 22

Information on WAND

- Class III Devices –total 1,261
 - Number cloned from DEAL 50
 - Number with EC certificate 688
 - FDA evidence 10
 - TGA evidence 8
 - No Conformity Assessment Evidence 505

Number of Notifications identifying the EC country of manufacture – 16 Oct 05

| EU Country | Device Notification | Class I | Class I Sterile | Class I Measurement | Class IIa | Class IIb | Class III | AIMD |
|----------------|---------------------|---------|-----------------|---------------------|-----------|-----------|-----------|------|
| Austria | 37 | 7 | 5 | | 13 | 12 | | |
| Belgium | 113 | 22 | 1 | 0 | 31 | 37 | 22 | |
| Denmark | 242 | 101 | 26 | 5 | 77 | 22 | 11 | |
| Finland | 58 | 32 | 0 | 0 | 4 | 17 | 5 | |
| France | 930 | 93 | 47 | 8 | 495 | 240 | 44 | 0 |
| Germany | 2317 | 1289 | 41 | 11 | 607 | 284 | 67 | 18 |
| Greece | 0 | | | | | | | |
| Ireland | 199 | 25 | 4 | 1 | 83 | 53 | 33 | 0 |
| Italy | 244 | 117 | 4 | 8 | 75 | 32 | 8 | 0 |
| Luxembourg | 0 | | | | | | | |
| Netherlands | 232 | 31 | 5 | 6 | 96 | 52 | 29 | 13 |
| Portugal | 9 | 3 | 3 | 0 | 3 | | | |
| Spain | 16 | 5 | 1 | 0 | 5 | 5 | | |
| Sweden | 233 | 127 | 18 | 5 | 54 | 26 | 3 | 0 |
| England | 1198 | 782 | 77 | 22 | 188 | 113 | 16 | 0 |
| United Kingdom | 688 | 291 | 51 | 6 | 222 | 92 | 26 | 0 |
| Czech | 2 | 1 | | 1 | | | | |
| Malta | 1 | | 1 | | | | | |
| Turkey | 1 | | | 1 | | | | |
| Lithuania | 40 | 1 | 0 | 0 | 36 | 3 | | |
| Total | 6560 | 2927 | 284 | 74 | 1989 | 988 | 264 | 31 |

Number of Notifications identifying the country of manufacture – 16 Oct 05

| Country | Device Notifications | Class I | Class I Sterile | Class I measurement | Class IIa | Class IIb | Class III | AIMD |
|---------------|----------------------|---------|-----------------|---------------------|-----------|-----------|-----------|------|
| Australia | 926 | 519 | 110 | 7 | 204 | 51 | 17 | 18 |
| New Zealand | 370 | 219 | 48 | 5 | 52 | 44 | 2 | 0 |
| United States | 7923 | 3044 | 461 | 130 | 2164 | 1047 | 907 | 170 |
| USA | 196 | 111 | 3 | 8 | 36 | 37 | 1 | 0 |

IMPORTANT

- New products must be entered on WAND
 - Entries on WAND must be maintained
-until commencement of the Single Agency