



SINGAPORE, 24 OCTOBER 2014

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.
HSA UPDATES NO 2/2014

HSA UPDATES ON APPROVED LIST OF CLASS B THERMOMETERS

The Health Sciences Authority (HSA) has found that some digital and infrared thermometers classified as medium risk Class B devices, that are being supplied and sold in Singapore have not been registered. HSA would like to reassure consumers that while these thermometers are unregistered, based on post marketing surveillance in Singapore, no safety or quality issues or any adverse events have been detected or reported to date.

2 To address the administrative oversight of some dealers in not registering their devices, HSA is currently working with the suppliers and retailers to remove all unregistered thermometers from the shelves and has sent out a circular to all its registrants, importers and wholesalers to remind them of the need to register the thermometers and to apply for the appropriate dealer licences. They have also been asked to stop any import, supply and sales of the unregistered thermometers immediately until the thermometers have been registered with HSA.

Consumer Advisory

3 Consumers are reminded to purchase from reliable retailers and not to purchase from internet websites, as the origin and quality of the thermometers cannot be verified. Consumers may also wish to refer to the list of registered Class B thermometers in **Annex A**.

4 Regarding the appropriate use of thermometers, patients and caregivers are advised to seek medical attention promptly if they have any health concerns, irrespective of their temperature readings from the thermometer, as temperature is only one of the parameters used in the management of any patients with fever. Patients and caregivers should consider other factors such as age, concurrent medical conditions, presence of other symptoms (such as chills or shivering), and general well-being of the patient.

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

LIST OF REGISTERED CLASS B THERMOMETERS (AS AT 20 OCT 2014)

| Registration # | Registered Thermometers |
|----------------|--|
| DE0012553 | Ascen Resources Takamizu Digital Thermometer |
| DE0010579 | Beurer digital thermometer |
| DE0012990 | Beurer Infrared Ear & Forehead Thermometer |
| DE0012991 | Beurer Infrared Ear Thermometer |
| DE0012989 | Beurer Infrared Forehead Thermometer |
| DE0010534 | Braun Behind Ear Thermometer |
| DE0013544 | Bremed Bluebeam No Contact Thermometer |
| DE0012103 | Bremed Digital Thermometer |
| DE0000386 | CADI T560 Clinical Ear & Forehead Thermometer |
| DE0012210 | Cadi.Sense Wireless Thermometer |
| DE0500051 | CEM Non-Contact Forehead InfraRed Thermometer |
| DE0003439 | Covidien Filac™ Electronic Thermometer |
| DE0003440 | Covidien Genius™ Tympanic Thermometer |
| DE0500244 | Digital Thermometer |
| DE0008828 | Famidoc Digital Clinical Thermometer |
| DE0007940 | First Choice Digital Thermometer |
| DE0008623 | FORA IR20 Ear Thermometer |
| DE0007772 | Guardian Digital Ear Thermometer IET1 Series |
| DE0008006 | Guardian Digital Ovulation thermometer (DT-02) |
| DE0008835 | Guardian Digital Ovulation Thermometer (DT-12) |
| DE0007682 | Guardian Digital Thermometer (BT-A21CN) |
| DE0008005 | Guardian Digital Thermometer (DT-K01A) |
| DE0008836 | Guardian Digital Thermometer (DT-K11A) |

| Registration # | Registered Thermometers |
|-----------------------|--|
| DE0007782 | Guardian Infrared Ear & Forehead Thermometer FET1 series |
| DE0008617 | Hangzhou Hua'an Digital Thermometer (DT-01D, 02, 01B, 12, K01A) |
| DE0012785 | Hangzhou Hua'an Digital Thermometer (DT-11B, 11D, 11E, 11G, 02, 12, 101A, 101B, 111A, 111B, 111D, 111G, K01A, K11A, K11B, K101A, K111A, K111B, K111D, Y111D) |
| DE0002934 | Hartmann ThermoVal® Classic Electronic Thermometer |
| DE0004111 | Hartmann ThermoVal® Rapid Electronic Thermometer |
| DE0008631 | Hubdic Non-Contact Infrared Thermometer |
| DE0007590 | Hubdic Thermofinder FS-300 Non-Contact Infrared Thermometer |
| DE0011800 | Incontech 4 in 1 Infrared Thermometer BT-A41CN |
| DE0011801 | Incontech Body Infrared thermometer BL-KT812 |
| DE0013545 | Incontech Digital Thermometer |
| DE0010953 | Incontech Infrared Ear Thermometer |
| DE0011802 | Incontech Non-contact infrared medical thermometer NC-9900 |
| DE0007999 | Jinxinbao Rycom Non-contact Infrared Thermometer |
| DE0500249 | Jitron - Digital Thermometer JTMD-201M |
| DE0004281 | Jitron Ear & Forehead Thermometer TM401M |
| DE0011331 | Jitron Ear and Forehead Thermometer |
| DE0011246 | Kawa Digital Thermometer |
| DE0005300 | Kaz Braun Thermoscan Infra Red Thermometer |
| DE0004345 | Kaz Braun Thermoscan IRT4520 Infrared Ear Thermometer |
| DE0006110 | Medicare Infrared Thermometer |
| DE0500104 | Mesure Digital Thermometer |
| DE0012217 | NewForm TechArt Pte Ltd / NewFresh Digital Infrared Thermometer NT100 (Ear & Forehead Type) |
| DE0007560 | NTUC Unity Healthcare Digital Thermometer |
| DE0000629 | Omron Digital Thermometer (MC-272L, 270, 271W) |

| Registration # | Registered Thermometers |
|-----------------------|--|
| DE0007676 | Omron Digital Thermometer (MC-245, 246,341, 343F) |
| DE0011782 | Omron Ear Thermometer TH839S |
| DE0001560 | Omron Gentle Temp Ear Thermometer |
| DE0009562 | OSIM uScan Digital Thermometer |
| DE0008029 | Progress Healthcare Acuset Digital Thermometer |
| DE0013697 | Rossmax Digital Thermometers |
| DE0014897 | Rossmax Infrared Ear Thermometer |
| DE0014896 | Rossmax Non-Contact Temple Thermometer |
| DE0008612 | Rycom Non-contact Infrared Thermometer |
| DE0012625 | Shanghai Hua Chen digital thermometer DT-1TB |
| DE0010581 | Smitech Digital Thermometer |
| DE0007440 | Tecnimed Thermofocus non-contact thermometer 01500 series |
| DE0012860 | Tecnimed VisioFocus non-contact Clinical infrared thermometer. |
| DE0011609 | Terumo Digital Clinical Thermometer |
| DE0007795 | Terumo Ear Thermometer |
| DE0500192 | Visiomed ThermoFlash Medical No Contact Thermometer |
| DE0010571 | Watsons Digital Thermometer |
| DE0008642 | Welch Allyn Braun Thermoscan Pro 4000 Ear Thermometer |
| DE0003540 | Welch Allyn® SureTemp® Electronic Thermometer |
| DE0003543 | Welch Allyn® SureTemp® Plus Thermometer |
| DE0500166 | Yukin Yukare Digital Thermometer |
| DE0007593 | Zohra Wahab Sakura Digital Clinical Thermometer |