



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