Manufacturers of dental impression materials, surgical instruments or abutments breathed a sigh of relief on Friday when the Singapore Health Science Authority (HAS) announced that it would lower its regulatory requirements for low risk medical devices, today international has learned. Registration fees for Class B products like dental abutments and scaling systems will also be lowered soon, the government agency responsible for medical product regulations said on Friday.

Beginning in May, manufacturers of Class A devices will only be required to register their devices with HAS for the purpose of market monitoring. This change however will not include sterile devices. The registration fees for approximately $6,000, Class B products will be reduced from $62,300 to $31,400 from September.

The organisation has also said that it will look into revising fees for Special Authorisation Route registrations and regulations for higher risk Class C and D devices.

According to the HAS, about 70 per cent of all medical devices registered in Singapore currently fall under Classes A and B. The changes are expected to facilitate the import of medical and dental equipment into the city-state, whose health care device market is estimated to be worth more than $550 million.

“These changes reflect a flexible and responsive regulator that is willing to listen to the teething issues faced by the industry with the introduction of medical device regulation in Singapore, without compromising patients’ well-being,” Dr Amy Khor Lean Suan, Minister of State at the Ministry of Health, said. “I am confident that these enhancements, for lower risk devices in particular, will address the concerns of the industry and that HAS will continue to enhance the framework to facilitate access to safe medical devices.”

Since 2008, medical devices, including dental equipment, have had to be registered with the HAS. Prior to that, regulation was voluntary and followed international regulatory standards, like those of the US Food and Drug Administration. The guidelines have continuously sparked unrest among industry stakeholders over the past few years who blamed the regulations for preventing medical and dental practitioners in Singapore from using state of the art equipment and for increasing health care costs.

For dental consumers and sterilisation equipment suppliers, Euromed, this is its third exhibition in Singapore. Executive Director of the Expo, Andrea Pasquato said that Chinese dental and medical companies are the petticoat in the region but there is a great demand for products “made in Italy”. Owing to their high quality and innovative design, European goods are appreciated in the Far East and able to compete with the cheaper market in China, he said.

According to UNIDI, the Italian industry is third worldwide in terms of volume of business, technology innovation and exports. The association’s 2011 dental market report revealed that Italian dental production amounted to €400 million, and dental business is the biggest contributor in the region.

For the first time, the Italian Dental Industries Association (UNIDI) has brought together 25 companies at the Italian pavilion at IDEM Singapore. The association and its members have recognised a demand for European dental products in the South-East Asian market and thus see great opportunities for Italian manufacturers in the region.

According to Gianfranco Berrettini, Director of UNIDI’s Executive Board, about 20 Italian companies already have operations in Asia. He said he considers Singapore a location with great potential, offering operators the opportunity to canvass the entire Far East from Indonesia to Thailand.

This year’s Italian pavilion comprises companies that are already experienced in this market and some newcomers, exhibiting their dental products and equipment for dental laboratories, as well as for dental practitioners in particular.

For example, the medical technology provider Mectron opened its regional headquarters in Phuket, Thailand, about five years ago. The main reason for this was to provide more effective customer service to the region, according to Norbert Emmerich, Managing Director of Mectron Asia Pacific. Since then, the supplier has been able to reduce its expenses on shipping by 80 per cent and the required time for repair services has shrunken from two months to one week, he said.

The Asian market is viewed as offering great prospects by dental business newcomers such as EGS, specialist in 3D scanning software from the Italian province of Bologna, exhibiting for the first time at IDEM Singapore. Prior to the fair’s opening, Emidio Cennerilli, General Manager of EGS, told today international that he is curious about the opportunities that the South-East Asian dental market holds for his company.

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