PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Ref : (13)KK(S)-602(31)Jld.2
Date : 11 March 2014

To whom it may concern

MEDICAL DEVICE ACT (ACT 737) AND MEDICAL DEVICE AUTHORITY ACT (ACT 738)

We refer to the abovementioned and the present enquires about it.

2. This is to inform that Act 737 and Act 738 has been gazetted and came in to force on 1st July 2013 and 15th March 2012 respectively.

3. With the coming into force of the above, the Medical Device Industry in Malaysia is now entering a regulated environment in which by virtue of Section 5 of Act 737, medical device intended for import, export or placement in market shall be registered and concurrently, Section 15 Act 737 requires establishments to apply for licensing post registration.

4. Furthermore, Section 80 of the Act provides for a 2 years grace period for registration of medical device and 1 year for licensing application. Hence, the requirement for registration is mandatory on the 1st July 2015 while licensing requirement is mandatory by 1st of July 2014.

5. As to that effect, the Medical Device Authority encourages compliance by the stakeholders to submit to the above mentioned requirement as stated in para 4 in order to safeguard interest especially with the oncoming of the mandatory phase very soon. We are happy to engage in any enquiries regarding the above mentioned subject and a seminar for government agencies will be conducted soon in April 2014.

Thank you.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(ZAMANE BIN ABDUL RAHMAN)
Chief Executive
Medical Device Authority
Ministry of Health, MALAYSIA