WEBSITE ANNOUNCEMENT

PUBLIC COMMENT: GUIDANCE DOCUMENT ON CONTRACT MANUFACTURER - LICENSING AND MEDICAL DEVICE REGISTRATION REQUIREMENTS FOR THE PURPOSE OF MEDICAL DEVICE EXPORT AND CERTIFICATE OF FREE SALE (CFS) APPLICATION

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following;

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

The draft document is open for comments and feedback.

To view draft of document CLICK HERE

To download feedback form, CLICK HERE

Please submit your feedback to norfazila@mdb.gov.my before 25th March 2018.