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

Our Ref: (8) dlm. MDA. 100-1/8/5
Date : 22 May 2014

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 5 YEAR 2014

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL DEVICE ACT 2012 (ACT 737):

CERTIFICATION OF GOOD MANUFACTURING PRACTICE (GMP) FOR THE PURPOSE OF OBTAINING ESTABLISHMENT LICENSE

PURPOSE

1) The purpose of this circular is to set the policy for implemention and enforcement under the medical device Act 2012 (Act 737) relating to GMP certification issued by National Pharmaceutical Control Bureau (NPCB) for the purpose of obtaining establishment license.

BACKGROUND

2) In accordance with Regulation 11(1) of the Third Schedule, Conformity Assessment Procedure, Medical Device Regulation 2012, for the purpose of placement of a medical device in the market, manufacturer, authorised representative, importers and distributers of medical devices shall develop, maintain and implement an appropriate quality management system which commensurates with the role and function of the establishment and comply with the requirements in the following table:

Type of Establishment	Quality Management System
(a) Manufacturer	ISO 13485 – Medical devices – quality Management System – Requirements for regulatory purposes
(b) Authorised representative	Good Distribution Practice for Medical Devices (GDPMD)
(c) Importer	Good Distribution Practice for Medical Devices (GDPMD)
(d) Distributor	Good Distribution Practice for Medical Devices (GDPMD)

3) To date, there are some establishments who wish to apply a establishment licenses using GMP certification issued by NPCB.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) **The Medical Device Authority Meeting No. 6/2013 has decided to set the policy implementation and enforcement as follows**:

Medical Device Authority (MDA) accepts GMP certification issued by NPCB, only during the transition period. The transition period is effective from 1st July 2013 until 1st July 2014. Nevertheless, establishments with GMP certification shall obtain the ISO 13485 certification during the transitional period.

USAGE AND EFFECTIVE DATE

5) Circular issued shall be used as part of requirements under Act 737 and this circular shall be effective from the date it is issued.

ENQUIRIES

6) Any enquiries relating to this Circular can be forwarded to:

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Medical Device Authority
Ministry of Health Malaysia
Level 5, Menara Prisma, No. 26
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62675 Putrajaya, MALAYSIA
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Thank you.

"BERKHIDMAT UNTUK NEGARA"

(Y. BHG. DATUK DR. NOOR HISHAM B ABDULLAH)
Chairman
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