



CERTIFICATE



SIRIM



MDQMS 30092015 CB 04



SIRIM QAS International Sdn. Bhd. hereby certifies that

MEDISAFE TECHNOLOGIES SDN. BHD.
NO. 17, LEKAS 23, JALAN BESI 1/1
KAWASAN PERINDUSTRIAN SUNGAI PURUN
43500 SEMENYIH
SELANGOR DARUL EHSAN
MALAYSIA

has implemented a Quality Management System for Medical Devices complying with

ISO 13485 : 2016

Medical Devices - Quality Management System – Requirements For Regulatory Purposes
(In Compliance with Act 737 and Medical Device Regulations 2012 requirements)

Scope of Certification

MANUFACTURE OF IV CATHETER, ENDOTRACHEAL, TUBE, FOLEY CATHETERS AND IV INFUSION SET.

RISK CLASSIFICATION OF MEDICAL DEVICE: CLASS B (RULE 5).

Issue Date : 25 November 2019

Original certification date : 25 November 2019

Expiry Date : 24 November 2022

Certification No. : QMS-MD 00148

SIRIM QAS International Sdn. Bhd.
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MOHD AZANUDDIN SALLEH

Chief Executive Officer

SIRIM QAS International Sdn. Bhd.

This certificate is granted subject to the terms and conditions as stated in the Certification Agreement.