



CERTIFICATE



SIRIM QAS International Sdn. Bhd. hereby certifies that

SMT TECHNOLOGIES SDN. BHD.
PLOT 102 & 102A
BAKAR ARANG INDUSTRIAL ESTATE
08000 SUNGAI PETANI
KEDAH DARUL AMAN
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

- 1) MANUFACTURE OF PRINTED CIRCUIT BOARD ASSEMBLIES AND COMPLETE BOX BUILT FOR AUTOMATED EXTERNAL DEFIBRILLATORS;
- 2) MANUFACTURE OF PLASTIC PARTS BY INJECTION MOULDING PROCESS;
- 3) MANUFACTURE OF SURGICAL FACE MASKS.

RISK CLASSIFICATION OF MEDICAL DEVICES :

- SCOPE 1 & 2 - CLASS 2 (FDA) (FOR THE INTENDED MEDICAL DEVICE)
- SCOPE 3 - CLASS A (MDA RULE 4)

Issue Date : 27 July 2020
Original certification date : 09 September 2011
Expiry Date : 08 September 2023
Certification No. : QMS-MD 00105

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SIRIM QAS International Sdn. Bhd.

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