Reference Number: **(26) MDA.600-1/1/18 JILID 4**
Revision Date: **NOVEMBER 18, 2021**

KGS CERTIFICATION SDN. BHD.
NO. 15 LORONG BLM 5/4 BANDAR
LAGUNA MERBOK
08000 SUNGAI PETANI
KEDAH DARUL AMAN
TEL: **+604-441 1524**
FAX: **+604-441 0610**

PERSON RESPONSIBLE:
PN. NACHEYAKALA A/P ELUMALAI
[admin@kgscert.com**]**

CONTACT PERSON:
MS. NURUL IZZATI BINTI ABDUL GHANI
[admin@kgscert.com**]**

CAB REGISTRATION NUMBER: **MDA/CAB-013**
VALIDITY: **12/11/2021 – 11/11/2024**

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS)		
1	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
2	GDPMD	Good Distribution Practice for Medical Devices

Conformity Assessment of Technical Documentation		
3	MD 0103	Non-active orthopaedic and rehabilitation devices
4	MD 0104	Non-active medical devices with measuring function
5	MD 0106	Non-active instruments
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	IVD 0403	Immunology
8	IVD 0404	Molecular biology
9	IVD 0406	Specimen receptacles
10	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
11	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

Section 10(1), Medical Device Act 2012 (Act 737) and Regulation 8, Medical Device Regulations 2012