LIST OF REGISTERED CONFORMITY ASSESSMENT BODY

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

NO.	CAB	REGISTRATION NO.	LINK
1	TÜV SÜD (MALAYSIA) SDN. BHD.	MDA/CAB-001	Go to LIST
2	SGS (MALAYSIA) SDN. BHD.	MDA/CAB-003	Go to LIST
3	SIRIM QAS INTERNATIONAL SDN. BHD.	MDA/CAB-004	Go to LIST
4	BSI SERVICES MALAYSIA SDN. BHD.	MDA/CAB-005	Go to LIST
5	DQS CERTIFICATION (M) SDN. BHD.	MDA/CAB-006	Go to LIST
6	TÜV RHEINLAND MALAYSIA SDN. BHD.	MDA/CAB-007	Go to LIST
7	TÜV NORD (MALAYSIA) SDN. BHD.	MDA/CAB-008	Go to LIST
8	CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.	MDA/CAB-009	Go to LIST
9	CI INTERNATIONAL CERTIFICATION SDN. BHD.	MDA/CAB-012	Go to LIST
10	KGS CERTIFICATION SDN. BHD.	MDA/CAB-013	Go to LIST
11	DNV GL INTERNATIONAL SDN. BHD.	MDA/CAB-014	Go to LIST
12	GENUINE DIAMOND SDN. BHD.	MDA/CAB-016	Go to LIST
13	ASI CERTIFICATION SDN. BHD.	MDA/CAB-019	Go to LIST
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15	KIWA INTERNATIONAL CERTIFICATIONS (M) SDN. BHD.	MDA/CAB-021	Go to LIST
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19	LEADER CERTIFICATION SDN. BHD.	MDA/CAB-025	Go to LIST
20	INTERTEK CERTIFICATION INTERNATIONAL SDN. BHD.	MDA/CAB-026	Go to LIST
21	STRAIT CERTIFICATION SDN. BHD.	MDA/CAB-027	Go to LIST
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23	PRECISION MANAGEMENT CERTIFICATION (PMC) SDN. BHD.	MDA/CAB-029	Go to LIST
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Revised by: **CAB Registration Unit (CABRU)**
Initial: **January 1, 2023**, Revision: **10 December 2025**

CAB REGISTRATION NUMBER: **MDA/CAB-001**
VALIDITY: **21/11/2025 – 20/11/2028**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0105	Non-active ophthalmologic devices
8	MD 0106	Non-active instruments
9	MD 0107	Contraceptive medical devices
10	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
11	MD 0201	Non-active cardiovascular implants
12	MD 0202	Non-active orthopedic implants
13	MD 0203	Non-active functional implants
14	MD 0204	Non-active soft tissue implants
15	MD 0301	Bandages and wound dressings
16	MD 0303	Other medical devices for wound care
17	IVD 0101	AB0 system
18	IVD 0201	HIV infection (HIV 1 and 2)
19	IVD 0203	Hepatitis B, C and D
20	IVD 0401	Clinical chemistry
21	IVD 0405	Pregnancy and ovulation
22	IVD 0406	Specimen receptacles
23	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
24	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-003**
VALIDITY: **21/11/2025 – 20/11/2028**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0105	Non-active ophthalmologic devices
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	MD 0204	Non-active soft tissue implants
8	MD 0301	Bandages and wound dressings
9	MD 0303	Other medical devices for wound care
10	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
11	MD 1104	Active surgical devices
12	MD 1109	Active devices for patient positioning and transport
13	MD 1202	Imaging devices utilizing non-ionizing radiation
14	MD 1301	Monitoring devices of non-vital physiological parameters
15	MD 1302	Monitoring devices of vital physiological parameters
16	IVD 0304	Hereditary disease: phenylketonuria
17	IVD 0307	Tumoral marker: PSA
18	IVD 0404	Molecular biology

Conformity Assessment by Way of Verification		
19	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-004**
VALIDITY: **21/11/2025 – 20/11/2028**

SIRIM QAS INTERNATIONAL SDN. BHD.
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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0202	Non-active orthopaedic implants
10	MD 0203	Non-active functional implants
11	MD 0204	Non-active soft tissue implants
12	MD 0301	Bandages and wound dressings
13	MD 0302	Suture material and clamps
14	MD 0303	Other medical devices for wound care
15	MD 0402	Dental materials
16	MD 0403	Dental implants
17	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
18	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
19	MD 1104	Active surgical devices
20	MD 1106	Active dental devices
21	MD 1107	Active devices for disinfection and sterilisation
22	MD 1109	Active devices for patient positioning and transport
23	MD 1111	Software
	MD 1201	Imaging devices utilizing ionizing radiation
	MD 1202	Imaging devices utilizing non-ionizing radiation
24	MD 1301	Monitoring devices of non-vital physiological parameters
25	MD 1302	Monitoring devices of vital physiological parameters
26	IVD 0203	Hepatitis B, C and D
27	IVD 0303	Congenital infections: rubella, toxoplasmosis
28	IVD 0307	Tumoral marker: PSA
29	IVD 0401	Clinical chemistry

30	IVD 0404	Molecular biology
31	IVD 0405	Pregnancy and ovulation
32	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
33	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
34	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-005**
VALIDITY: **21/11/2025 – 20/11/2028**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	*MD 0402	Dental materials
5	MD 1301	Monitoring devices of non-vital physiological parameters
6	MD 1302	Monitoring devices of vital physiological parameters
7	IVD 0401	Clinical chemistry
8	IVD 0404	Molecular biology

* means approval only for conformity assessment on dental dam.

Conformity Assessment by Way of Verification		
9	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-006**
VALIDITY: **11/09/2023 – 10/09/2026**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0107	Contraceptive medical devices

Conformity Assessment by Way of Verification		
5	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-007**
VALIDITY: **11/09/2023 – 10/09/2026**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
8	MD 0202	Non-active orthopaedic implants
9	MD 0301	Bandages and wound dressings
10	MD 0401	Non-active dental equipment and instruments
11	MD 0402	Dental materials
12	MD 1104	Active surgical devices
13	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
14	IVD 0201	HIV infection (HIV 1 and 2)
15	IVD 0202	HTLV I and II
16	IVD 0203	Hepatitis B, C and D
17	IVD 0303	Congenital infections: rubella, toxoplasmosis
18	IVD 0305	Human infections: cytomegalovirus, chlamydia
19	IVD 0307	Tumoral marker: PSA
20	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
21	IVD 0401	Clinical chemistry
22	IVD 0403	Immunology
23	IVD 0405	Pregnancy and ovulation
24	IVD 0406	Specimen receptacles

Conformity Assessment by Way of Verification		
25	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-008**
VALIDITY: **11/09/2023 – 10/09/2026**

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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 0106	Non-active instruments
4	MD 0107	Contraceptive medical devices
5	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
6	MD 1111	Software
7	MD 1301	Monitoring devices of non-vital physiological parameters

Conformity Assessment by Way of Verification		
8	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-009**
VALIDITY: **12/02/2024 – 11/02/2027**

CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.
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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0106	Non-active instruments
6	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
7	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
8	MD 1201	Imaging devices utilizing ionizing radiation
9	MD 1202	Imaging devices utilizing non-ionizing radiation
10	MD 1302	Monitoring devices of vital physiological parameters
11	MD 1402	Devices utilising non-ionizing radiation
12	IVD 0401	Clinical chemistry
13	IVD 0403	Immunology
14	IVD 0404	Molecular biology
15	IVD 0406	Specimen receptacles
16	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
17	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-012**
VALIDITY: **25/06/2024 – 24/06/2027**

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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 0107	Contraceptive medical devices
4	MD 1111	Software

Conformity Assessment by Way of Verification		
5	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-013**
VALIDITY: **12/11/2024 – 11/11/2027**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
3	MD 0105	Non-active ophthalmologic devices
8	MD 0106	Non-active instruments
9	MD 0107	Contraceptive medical devices
10	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
11	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
12	MD 0301	Bandages and wound dressings
13	MD 0303	Other medical devices for wound care
14	MD 1110	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
15	IVD 0401	Clinical chemistry
16	IVD 0403	Immunology
17	IVD 0404	Molecular biology
18	IVD 0406	Specimen receptacles
19	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
20	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-014**
VALIDITY: **18/05/2025 – 17/05/2028**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0105	Non-active ophthalmologic devices
7	MD 0106	Non-active instruments
8	MD 0107	Contraceptive medical devices
9	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
10	MD 0202	Non-active orthopedic implants
11	MD 0301	Bandages and wound dressings
12	MD 0302	Suture material and clamps
13	MD 0303	Other medical devices for wound care
14	MD 1107	Active devices for disinfection and sterilization

Conformity Assessment by Way of Verification		
15	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-016**
VALIDITY: **22/11/2024 – 21/11/2027**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	MD 0302	Suture material and clamps
11	MD 0303	Other medical devices for wound care
12	**MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
13	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
14	MD 1103	Devices for stimulation or inhibition
15	MD 1104	Active surgical devices
16	MD 1105	Active ophthalmologic devices
17	MD 1106	Active dental devices
18	MD 1107	Active devices for disinfection and sterilization
19	MD 1109	Active devices for patient positioning and transport
20	MD 1201	Imaging devices utilizing ionizing radiation
21	MD 1202	Imaging devices utilizing non-ionizing radiation
22	MD 1301	Monitoring devices of non-vital physiological parameters
23	MD 1302	Monitoring devices of vital physiological parameters
24	MD 1401	Devices utilizing ionizing radiation
25	MD 1402	Devices utilizing non-ionizing radiation
26	IVD 0101	AB0 system
27	IVD 0102	Rhesus (C, c, D, E, e)
28	IVD 0103	Anti-Kell
29	IVD 0201	HIV infection (HIV 1 and 2)
30	IVD 0202	HTLV I and II
31	IVD 0203	Hepatitis B, C and D
32	IVD 0301	Anti-Duffy and anti-Kidd
33	IVD 0302	Irregular anti-erythrocyte antibodies
34	IVD 0303	Congenital infections: rubella, toxoplasmosis
35	IVD 0305	Human infections: cytomegalovirus, chlamydia
36	IVD 0307	Tumoral marker: PSA

37	IVD 0401	Clinical chemistry
38	IVD 0402	Haematology
39	IVD 0403	Immunology
40	IVD 0404	Molecular biology
41	IVD 0405	Pregnancy and ovulation
42	IVD 0406	Specimen receptacles
43	MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
44	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
45	MDS 7206	IVDs in sterile condition
46	MDS 7210	IVDs utilizing material of human origin

** means approval only for conformity assessment on infusion medical devices.

Conformity Assessment by Way of Verification		
47	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-019**
VALIDITY: **12/11/2024 – 11/11/2027**

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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 0101	Non-active devices for anaesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0106	Non-active instruments
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
10	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
11	MD 1103	Devices for stimulation or inhibition
12	MD 1104	Active surgical devices
13	MD 1105	Active ophthalmologic devices
14	MD 1106	Active dental devices
15	MD 1107	Active devices for disinfection and sterilization
16	MD 1108	Active rehabilitation devices and active prostheses
17	MD 1109	Active devices for patient positioning and transport
18	MD 1201	Imaging devices utilizing ionizing radiation
19	MD 1202	Imaging devices utilizing non-ionizing radiation
20	MD 1302	Monitoring devices of vital physiological parameters
21	MD 1401	Devices utilising ionizing radiation
22	MD 1402	Devices utilising non-ionizing radiation
23	MD 1403	Devices for hyperthermia / hypothermia
24	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
25	IVD 0404	Molecular biology
26	IVD 0406	Specimen receptacles
27	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
28	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
29	MDS 7206	IVDs in sterile condition
30	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
31	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-020**
VALIDITY: **04/04/2025 – 03/04/2028**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0105	Non-active ophthalmologic devices
8	MD 0106	Non-active instruments
~~9~~	~~MD 0107~~	~~Contraceptive medical devices~~
10	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
11	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
12	MD 0301	Bandages and wound dressings
14	MD 0302	Suture material and clamps
15	MD 0303	Other medical devices for wound care
16	MD 0401	Non-active dental equipment and instruments
17	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
18	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
19	MD 1103	Devices for stimulation or inhibition
20	MD 1104	Active surgical devices
21	MD 1106	Active dental devices
22	MD 1108	Active rehabilitation devices and active prostheses
23	MD 1109	Active devices for patient positioning and transport
24	MD 1301	Monitoring devices of non-vital physiological parameters
25	MD 1302	Monitoring devices of vital physiological parameters
26	MD 1403	Devices for hyperthermia / hypothermia
27	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
28	IVD 0101	AB0 system
29	IVD 0102	Rhesus (C, C, D, E, E)
30	IVD 0201	HIV Infection (HIV 1 And 2)
31	IVD 0203	Hepatitis B, C and D
32	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
33	IVD 0401	Clinical chemistry
34	IVD 0402	Haematology
35	IVD 0403	Immunology

36	IVD 0404	Molecular biology
37	IVD 0405	Pregnancy and ovulation
38	IVD 0406	Specimen receptacles
39	~~MDS 7005~~	~~Medical devices referencing the Directive 89/686/EEC on personal protective equipment~~

Conformity Assessment by Way of Verification		
40	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-021**
VALIDITY: **04/04/2025 – 03/04/2028**

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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 0102	Non-active devices for injection, infusion, transfusion and dialysis
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	MD 0301	Bandages and wound dressings
8	MD 0303	Other medical devices for wound care
9	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
10	MD 1107	Active devices for disinfection and sterilization
11	MD 1202	Imaging devices utilizing non-ionizing radiation
12	IVD 0401	Clinical chemistry
13	IVD 0402	Hematology
14	IVD 0406	Specimen receptacles

Conformity Assessment by Way of Verification		
15	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-022**
VALIDITY: **17/06/2024 – 16/06/2027**

AQC TECHNICAL ASSESSORS (M) SDN. BHD.
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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 0105	Non-active ophthalmologic devices
6	MD 0106	Non-active instruments
7	MD 0108	Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing
8	MD 0301	Bandages and Wound Dressings
9	MD 0303	Other medical devices for wound care
10	MD 1102	Respiratory Devices, Including Hyperbaric Chambers for Oxygen Therapy, Inhalation Anaesthesia
11	MD 1103	Devices for Stimulation or Inhibition
12	MD 1105	Active ophthalmologic devices
13	MD 1107	Active devices for disinfection and sterilisation
14	MD 1108	Active Rehabilitation Devices and Active Prostheses
15	MD 1109	Active Devices for Patient Positioning and Transport
16	MD 1402	Devices Utilising Non-Ionizing Radiation
17	IVD 0101	AB0 System
18	IVD 0102	Rhesus (C, C, D, E, E)
19	IVD 0103	Anti-Kell
20	IVD 0201	HIV Infection (HIV 1 And 2)
21	IVD 0202	HTLV I and II
22	IVD 0203	Hepatitis B, C And D
23	IVD 0301	Anti-Duffy And Anti-Kidd
24	IVD 0302	Irregular anti-erythrocyte antibodies
25	IVD 0303	Congenital infections: rubella, toxoplasmosis
26	IVD 0305	Human Infections: Cytomegalovirus, Chlamydia
27	IVD 0306	HLA tissue groups: DR, A, B
28	IVD 0307	Tumoral Marker: PSA
29	IVD 0309	Devices for Self-Diagnosis: Device for The Measurement of Blood Sugar
30	IVD 0401	Clinical Chemistry
31	IVD 0402	Haematology
32	IVD 0403	Immunology
33	IVD 0404	Molecular biology
34	IVD 0405	Pregnancy and ovulation
35	IVD 0406	Specimen Receptacles

36	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
37	MDS 7206	IVDs in sterile condition
38	MDS 7207	IVDs utilizing micromechanics

Conformity Assessment by Way of Verification		
39	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-023**
VALIDITY: **30/08/2025-29/08/2028**

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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 0106	Non-active instruments
5	MD 0301	Bandages and Wound Dressings

Conformity Assessment by Way of Verification		
6	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-024**
VALIDITY: **15/08/2023 – 14/08/2026**

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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 0106	Non-active instruments
4	MD 0301	Bandages and wound dressings

Conformity Assessment by Way of Verification		
5	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-025**
VALIDITY: **18/10/2023 - 17/10/2026**

LEADER CERTIFICATION SDN. BHD.
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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 orthopedic and rehabilitation devices
4	MD 0106	Non-active instruments
5	MD 0202	Non-active orthopedic implants
6	MD 0203	Non-active functional implants
7	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
8	IVD 0401	Clinical chemistry
9	IVD 0402	Hematology
10	IVD 0403	Immunology
11	IVD 0404	Molecular biology
12	IVD 0405	Pregnancy and ovulation
13	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
14	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-026**
VALIDITY: **04/07/2024 - 03/07/2027**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0105	Non-active ophthalmologic devices
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	IVD 0201	HIV infection (HIV 1 and 2)
11	IVD 0203	Hepatitis B, C and D
12	IVD 0401	Clinical chemistry
13	IVD 0403	Immunology
14	IVD 0404	Molecular biology

Conformity Assessment by Way of Verification		
15	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-027**
VALIDITY: **04/07/2024 - 03/07/2027**

STRAIT CERTIFICATION SDN. BHD.
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STRAIT CERTIFICATION SDN BHD

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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0103	Non-active orthopedic and rehabilitation devices
5	MD 0106	Non-active instruments
6	MD 0107	Contraceptive medical devices
7	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
8	MD 0201	Non-active cardiovascular implants
9	MD 0202	Non-active orthopedic implants
10	MD 0203	Non-active functional implants
11	MD 0204	Non-active soft tissue implants
12	MD 0301	Bandages and wound dressings
13	MD 0402	Dental materials
14	MD 0403	Dental implants
15	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
16	****MD 1103	Devices for stimulation or inhibition
17	IVD 0101	AB0 System
18	IVD 0102	Rhesus (C, C, D, E, E)
19	IVD 0103	Anti-Kell
20	IVD 0201	HIV infection (HIV 1 and 2)
21	IVD 0203	Hepatitis B, C and D
22	IVD 0301	Anti-Duffy And Anti-Kidd
23	IVD 0303	Congenital infections: rubella, toxoplasmosis
24	IVD 0305	Human infections: cytomegalovirus, chlamydia
25	IVD 0306	HLA tissue groups: DR, A, B
26	IVD 0307	Tumoral marker: PSA
27	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
28	IVD 0401	Clinical chemistry
29	IVD 0402	Hematology
30	IVD 0403	Immunology
31	IVD 0405	Pregnancy and ovulation
32	IVD 0406	Specimen receptacles
33	MDS 7001	Medical Devices Incorporating Medicinal Substances, According to Directive 2001/83/EC

34	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
35	MDS 7003	Medical Devices Incorporating Derivatives of Human Blood, According to Directive 2000/70/EC, Amended by Directive 2001/104/EC

**** means approval only for conformity assessment on Transcutaneous Electrical Nerve Stimulation (TENS) units.

Conformity Assessment by Way of Verification		
36	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-028**
VALIDITY: **24/06/2025 - 23/06/2028**

AMDEXT SDN. BHD.
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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 0104	Non-active medical devices with measuring function
4	MD 0106	Non-active instruments
5	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
6	IVD 0101	AB0 system
7	IVD 0102	Rhesus (C, C, D, E, E)
8	IVD 0103	Anti-Kell
9	IVD 0202	HTLV I and II
10	IVD 0203	Hepatitis B, C and D
11	IVD 0307	Tumoral marker: PSA
12	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
13	IVD 0401	Clinical chemistry
14	IVD 0403	Immunology
15	IVD 0404	Molecular biology
16	IVD 0405	Pregnancy and ovulation
17	IVD 0406	Specimen receptacles
18	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
19	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-029**
VALIDITY: **25/08/2025 - 24/08/2028**

PRECISION MANAGEMENT CERTIFICATION (PMC) SDN. BHD.
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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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0106	Non-active instruments
8	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
9	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
10	MD 1103	Devices for stimulation or inhibition
11	MD 1104	Active surgical devices
12	MD 1105	Active ophthalmologic devices
13	MD 1106	Active dental devices
14	MD 1107	Active devices for disinfection and sterilization
15	MD 1108	Active rehabilitation devices and active prostheses
16	MD 1109	Active devices for patient positioning and transport
17	MD 1201	Imaging devices utilizing ionizing radiation
18	MD 1202	Imaging devices utilizing non-ionizing radiation
19	MD 1302	Monitoring devices of vital physiological parameters
20	MD 1401	Devices utilizing ionizing radiation
21	MD 1402	Devices utilizing non-ionizing radiation
22	MD 1403	Devices for hyperthermia / hypothermia
23	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery

Conformity Assessment by Way of Verification		
24	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-030**
VALIDITY: **25/08/2025 - 24/08/2028**

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Medical Device AUTHORITY MALAYSIA

ARG INTERNATIONAL CERTIFICATION SDN BHD
ASSURANCE RECOGNITION GROWTH

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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
8	MD 0106	Non-active instruments
9	MD 0107	Contraceptive medical devices
10	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
12	MD 0301	Bandages and wound dressings
13	MD 0401	Non-active dental equipment and instruments
14	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
15	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
16	MD 1103	Devices for stimulation or inhibition
17	MD 1104	Active surgical devices
18	MD 1106	Active dental devices
19	MD 1107	Active devices for disinfection and sterilization
20	MD 1108	Active rehabilitation devices and active prostheses
21	MD 1109	Active devices for patient positioning and transport
22	MD 1301	Monitoring devices of non-vital physiological parameters
23	MD 1302	Monitoring devices of vital physiological parameters
24	MD 1403	Devices for hyperthermia / hypothermia
25	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
26	IVD 0201	HIV Infection (HIV 1 And 2)
27	IVD 0203	Hepatitis B, C and D
28	IVD 0305	Human infections: cytomegalovirus, chlamydia
29	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
30	IVD 0401	Clinical chemistry
31	IVD 0403	Immunology
32	IVD 0404	Molecular biology
33	IVD 0405	Pregnancy and ovulation
34	IVD 0406	Specimen receptacles
35	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment

Conformity Assessment by Way of Verification		
36	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

Note: **Blue**-in-colour font means 'new updated information'.

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

For more enquiries, please contact us:

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