CAB REGISTRATION NUMBER: **MDA/CAB-001**
VALIDITY: **21/11/2022 – 20/11/2025**

TÜV SÜD (MALAYSIA) 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 0107	Contraceptive medical devices
6	MD 0301	Bandages and wound dressings
7	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

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

CAB REGISTRATION NUMBER: **MDA/CAB-002**
VALIDITY: **21/11/2022 – 20/11/2025**

MEDCERT MALAYSIA 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 1111	Software
4	MD 1201	Imaging devices utilizing ionizing radiation
5	MD 1202	Imaging devices utilizing non-ionizing radiation
6	MD 1302	Monitoring devices of vital physiological parameters
7	MD 1402	Devices utilizing non-ionizing radiation

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

CAB REGISTRATION NUMBER: **MDA/CAB-003**
VALIDITY: **21/11/2022 – 20/11/2025**

SGS MALAYSIA 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 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

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

CAB REGISTRATION NUMBER: **MDA/CAB-004**
VALIDITY: **21/11/2022 – 20/11/2025**

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 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 0107	Contraceptive medical devices
5	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
6	MD 0202	Non-active orthopaedic implants
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 0403	Dental implants
11	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
12	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
13	MD 1104	Active surgical devices
14	MD 1106	Active dental devices
15	MD 1107	Active devices for disinfection and sterilisation
16	MD 1109	Active devices for patient positioning and transport
17	MD 1111	Software
18	IVD 0203	Hepatitis B, C and D
19	IVD 0303	Congenital infections: rubella, toxoplasmosis
20	IVD 0307	Tumoral marker: PSA
21	IVD 0401	Clinical chemistry
22	IVD 0404	Molecular biology
23	IVD 0405	Pregnancy and ovulation
24	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
25	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
26	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-005**
VALIDITY: **21/11/2022 – 20/11/2025**

BSI SERVICES MALAYSIA 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 0402	Dental materials
5	MD 1302	Monitoring devices of vital physiological parameters

**** means approval only for conformity assessment on dental dam.

Conformity Assessment by Way of Verification		
6	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**

TÜV RHEINLAND MALAYSIA 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 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 0202	Non-active orthopaedic implants
10	MD 0301	Bandages and wound dressings
11	MD 0401	Non-active dental equipment and instruments
12	MD 0402	Dental materials
13	IVD 0201	HIV infection (HIV 1 and 2)
14	IVD 0202	HTLV I and II
15	IVD 0203	Hepatitis B, C and D
16	IVD 0307	Tumoral marker: PSA
17	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
18	IVD 0401	Clinical chemistry
19	IVD 0403	Immunology
20	IVD 0405	Pregnancy and ovulation
21	IVD 0406	Specimen receptacles
22	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
23	VERIFICATION	Conformity Assessment by Way of Verification

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

TUV NORD (MALAYSIA) 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 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: **12/02/2021 – 11/02/2024**

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 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
5	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
6	MD 1202	Imaging devices utilizing non-ionizing radiation
7	MD 1302	Monitoring devices of vital physiological parameters

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

CAB REGISTRATION NUMBER: **MDA/CAB-012**
VALIDITY: **25/06/2021 – 24/06/2024**

CI INTERNATIONAL 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 0107	Contraceptive medical devices

Conformity Assessment by Way of Verification		
4	VERIFICATION	Conformity Assessment by Way of Verification

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

KGS 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 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

CAB REGISTRATION NUMBER: **MDA/CAB-014**
VALIDITY: **18/05/2022 – 17/05/2025**

DNV GL 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
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 orthopaedic 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 0302	Suture material and clamps
17	MD 0303	Other medical devices for wound care
18	MD 0401	Non-active dental equipment and instruments
19	MD 0402	Dental materials
20	MD 0403	Dental implants
21	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
22	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
23	MD 1103	Devices for stimulation or inhibition
24	MD 1104	Active surgical devices
25	MD 1106	Active dental devices
26	MD 1107	Active devices for disinfection and sterilization
27	MD 1108	Active rehabilitation devices and active prostheses
28	MD 1109	Active devices for patient positioning and transport
29	MD 1110	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
30	MD 1111	Software
31	MD 1301	Monitoring devices of non-vital physiological parameters
32	MD 1302	Monitoring devices of vital physiological parameters

Conformity Assessment by Way of Verification		
33	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-016**
VALIDITY: **22/11/2021 – 21/11/2024**

GENUINE DIAMOND 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 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	IVD 0101	AB0 system
25	IVD 0201	HIV infection (HIV 1 and 2)
26	IVD 0202	HTLV I and II
27	IVD 0203	Hepatitis B, C and D
28	IVD 0303	Congenital infections: rubella, toxoplasmosis
29	IVD 0305	Human infections: cytomegalovirus, chlamydia
30	IVD 0307	Tumoral marker: PSA
31	IVD 0401	Clinical chemistry
32	IVD 0402	Haematology
33	IVD 0403	Immunology
34	IVD 0404	Molecular biology
35	IVD 0405	Pregnancy and ovulation
36	IVD 0406	Specimen receptacles
37	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
38	MDS 7206	IVDs in sterile condition
39	MDS 7210	IVDs utilizing material of human origin

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

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

CAB REGISTRATION NUMBER: **MDA/CAB-019**
VALIDITY: **12/11/2021 – 11/11/2024**

ASI 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 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: **04/04/2022 – 03/04/2025**

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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 0106	Non-active instruments
8	MD 0107	Contraceptive medical devices
9	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
10	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
11	MD 0301	Bandages and wound dressings
12	MD 0302	Suture material and clamps
14	MD 0303	Other medical devices for wound care
15	MD 0401	Non-active dental equipment and instruments
16	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
17	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
18	MD 1103	Devices for stimulation or inhibition
19	MD 1104	Active surgical devices
20	MD 1106	Active dental devices
21	MD 1108	Active rehabilitation devices and active prostheses
22	MD 1109	Active devices for patient positioning and transport
23	MD 1301	Monitoring devices of non-vital physiological parameters
24	MD 1302	Monitoring devices of vital physiological parameters
25	MD 1403	Devices for hyperthermia / hypothermia
26	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
27	IVD 0305	Human infections: cytomegalovirus, chlamydia
28	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
29	IVD 0401	Clinical chemistry
30	IVD 0403	Immunology
31	IVD 0404	Molecular biology
32	IVD 0405	Pregnancy and ovulation
33	IVD 0406	Specimen receptacles
34	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment

35	MDS 7206	IVDs in sterile condition
36	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
37	VERIFICATION	Conformity Assessment by Way of Verification

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

CAB REGISTRATION NUMBER: **MDA/CAB-021**
VALIDITY: **04/04/2022 – 03/04/2025**

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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
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	MD 0303	Other medical devices for wound care
11	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
12	MD 1107	Active devices for disinfection and sterilization

Conformity Assessment by Way of Verification		
13	VERIFICATION	Conformity Assessment by Way of Verification

CAB REGISTRATION NUMBER: **MDA/CAB-022**
VALIDITY: **17/06/2021-16/06/2024**

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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 0108	Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing
6	MD 0301	Bandages and Wound Dressings
7	MD 1102	Respiratory Devices, Including Hyperbaric Chambers for Oxygen Therapy, Inhalation Anaesthesia
8	MD 1103	Devices for Stimulation or Inhibition
9	MD 1108	Active Rehabilitation Devices and Active Prostheses
10	MD 1109	Active Devices for Patient Positioning and Transport
11	MD 1402	Devices Utilising Non-Ionizing Radiation
12	IVD 0101	AB0 System
13	IVD 0102	Rhesus (C, C, D, E, E)
14	IVD 0103	Anti-Kell
15	IVD 0201	HIV Infection (HIV 1 And 2)
16	IVD 0203	Hepatitis B, C And D
17	IVD 0301	Anti-Duffy And Anti-Kidd
18	IVD 0305	Human Infections: Cytomegalovirus, Chlamydia
19	IVD 0307	Tumoral Marker: PSA
20	IVD 0309	Devices for Self-Diagnosis: Device for The Measurement of Blood Sugar
21	IVD 0401	Clinical Chemistry
22	IVD 0402	Haematology
23	IVD 0403	Immunology
24	IVD 0406	Specimen Receptacles

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

CAB REGISTRATION NUMBER: **MDA/CAB-023**
VALIDITY: **30/08/2022-29/08/2025**

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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 0301	Bandages and Wound Dressings

Conformity Assessment by Way of Verification		
4	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**

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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

Conformity Assessment by Way of Verification		
7	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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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