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Validity **MDA/CAB-004**: **21/11/2016 - 20/11/2019**

## SCOPE OF REGISTRATION

| **Conformity Assessment of Quality Management System (QMS)** | | |
|---|---|---|
| (1) | GDPMD | Good Distribution Practice for Medical Devices |
| (2) | ISO 13485 | Quality Management Systems for Medical Devices – Requirements for Regulatory Purpose |

| **Conformity Assessment of Medical Device Technical Areas** | | |
|---|---|---|
| (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 0107 | Contraceptive medical devices |
| (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 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 0402 | Dental materials |
| (17) | MD 0403 | Dental implants |
| (18) | MD 1301 | Monitoring devices of non-vital physiological parameters |
| (19) | MD 1302 | Monitoring devices of vital physiological parameters |
| (20) | MD 1403 | Devices for hyperthermia / hypothermia |
| (21) | IVD 0203 | Hepatitis B, C and D |
| (22) | IVD 0303 | Congenital infections: rubella, toxoplasmosis |
| (23) | IVD 0307 | Tumoral marker: PSA |
| (24) | IVD 0401 | Clinical chemistry |
| (25) | IVD 0404 | Molecular biology |
| (26) | IVD 0405 | Pregnancy and ovulation |
| (27) | IVD 0406 | Specimen receptacles |
| (28) | MDS 7002 | Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC |
| (29) | MDS 7005 | Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE) |

| **Conformity Assessment of Medical Device Technical Areas** | | |
|---|---|---|
| (30) | VERIFICATION | Conformity Assessment by Way of Verification |

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