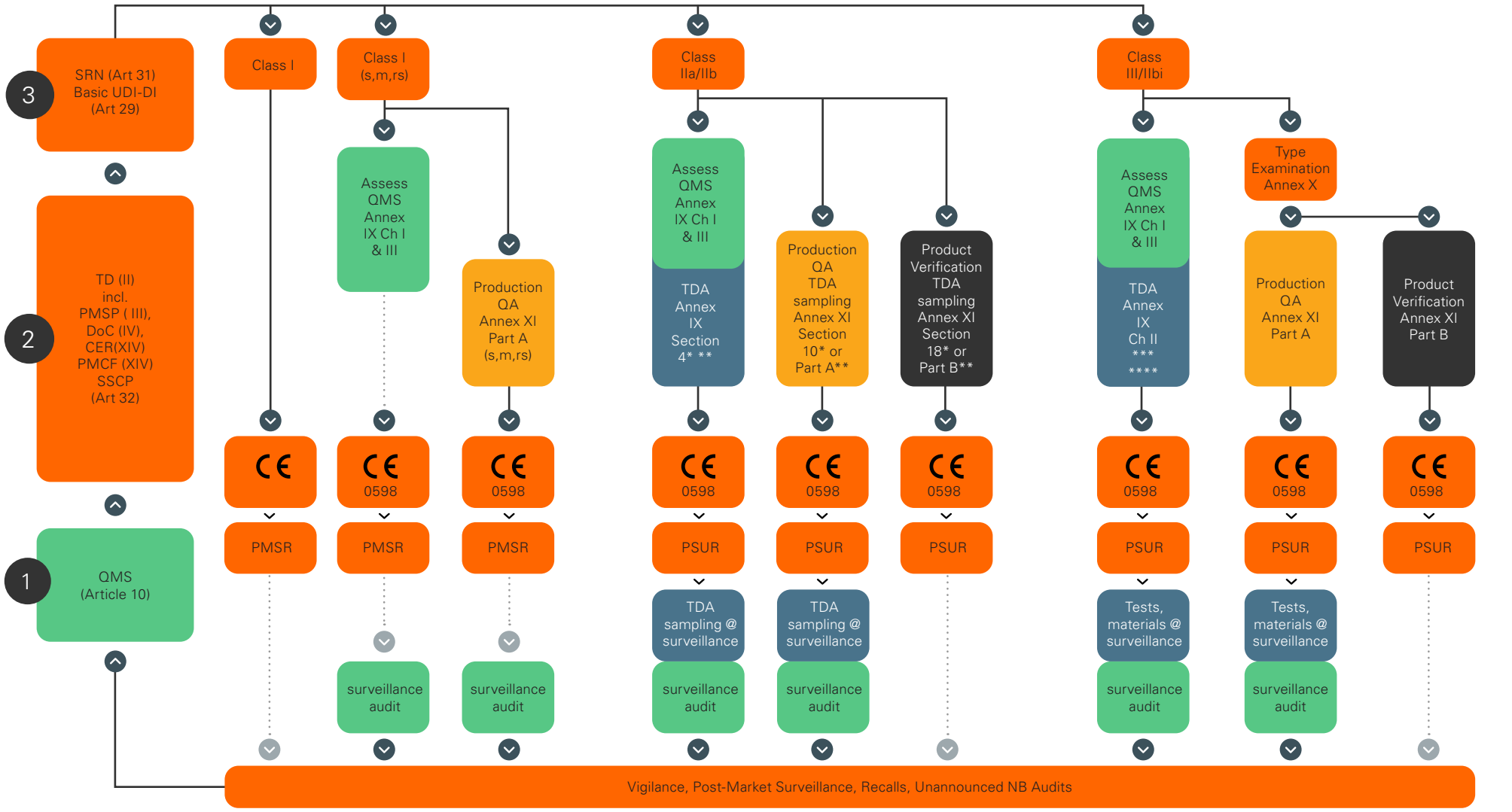
SGS Fimko Ltd.

CONFORMITY ASSESSMENT ROUTES IN MDR (EU) 2017/745, ARTICLE 52



LEGEND: EU QMS Certificate · EU TDA Certificate · EU Production QA Certificate · EU Product Verification Certificate · EU Type Examination Certificate

- * TDA – IIa: At least one representative device for each category of devices is assessed.
- ** TDA – IIb: Representative sample of generic device group selected and assessed. In case of an active device intended to remove or administer a medicinal substance, expert panel is involved.
- *** TDA – IIb implantable: 100% assessment (except sutures, staples, dental filings dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connecors).
- **** TDA – III implantable: 100% assessment, expert panel is involved.Surveillance audit every year. Unannounced audits at least once every five years, more otien based on risk class and frequency of nonconformities PSUR (Periodic Safety Update Report, Art 86) – update when necessary and at least every two years.
- PMSR (Post-Market Surveillance Report) - update when necessary.
- SSCP (Summary of Safety and Clinical Performance)
- DoC = Declaration of Conformity
- CER = Clinical Evaluation Report
- PMSP = Post-Market Surveillance Plan
- PMCF = PostMarket Clinical Follow-up,
- XIV, Part B - for Class III devices and implantable devices evaluation report
- updated at least annually, for others the schedule to be justified.
- UDI-DI = Unique Device Identification – Device Identifier
- SRN = Single Registration Number
- QMS = Quality Management System
- TDA = Technical Documentation Assessment

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