The tasks of Swissmedic – Lifecycle of a medical device

PHASE 1: DEVELOPMENT UP TO MARKET CONFORMITY
pre-market

1. Approve clinical trials
2. Designation and surveillance of the Conformity Assessment Bodies (CAB)
3. Mandatory notification for placing on the market (notifications according to MedDO Art. 6)
4. Exemptions
5. Export certificates (FSC)

PHASE 2: MARKET LAUNCH
(after market launch)

6. Exemptions
7. Market surveillance (MKM)
8. Inspections
9. Materiovigilance (MV)

PHASE 3: POST-MARKET SURVEILLANCE
(post-market)

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6. CAB audits manufacturer
7. Recertification by CAB
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