TECHNICAL DOCUMENTATION CHECKLIST FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES -ANNEXES II AND III OF IVDR (EU) 2017/746 ☐ Product/trade name, general description ☐ Risk Management Plan RISK ☐ Intended purpose and intended users **MANAGEMENT** Risk Management Methods, e.g. Preliminary Hazard Analysis, D-FMEA, P-FMEA, FTA, ☐ Classification HAZOP, HACCP **DEVICE DESCRIPTION** Risk Management Report, ☐ Description of the components/ingredients including benefit-risk analysis Description of appropriate or dedicated instruments & software Clinical Evaluation Plan & Report VALIDATION DATA ☐ Basic UDI-DI Information on analytical performance ■ Information on clinical performance Reference to previous and similar V&V generations of the device SUMMARY **DESIGN** Information on scientific validity REPORT VERIFICATION & VALIDATION Performance Evaluation Report: ☐ Labels **INFORMATION Analytical Performance Report SUPPLIED** ☐ IFUs ERIFICATION Scientific Validity Report DATA Clinical Performance Report ☐ Information on design stages applied Stability, EN ISO 23640 Description of the critical ingredients of the device such as antibodies, antigens, Software verificaltion & validation enzymes, nucleic acid primers provided or EN 62304 recomended for use with the device Analytical technology, description of the **DESIGN &** entire system, SW and HW MANUFACTURING Post Market Performance Follow Up (PMPF) **POST-MARKET** Plan & Report ☐ SW-algorithm **SURVEILLANCE** PMS Plan & Report (see Annex III of (EU) (ANNEX III) Periodic safety update report (PSUR) Identification of all sites, including suppliers and subcontractors, where manufacturing activities are performed List of applied standards including Common **GENERAL SAFETY** Technical Specifications AND PERFORMANCE file REOUIREMENTS ☐ GSPR Checklist / Matrix GSPR link to verification/validation including precise identity of evidence documents for each harmonized standard and Common **Medical Devices Regulatory Compliance** Your medical devices in a global market mdrc-consulting.com