**MANDATORY DOCUMENTATION CHECKLIST**

EMR vendor must submit ALL the documentation as per the checklist below. Failure to submit any of the documents will result in the Application being rejected.

| **#** | **DOCUMENT** |
| --- | --- |
| **A** | **ISO Certificate 13485** The EMR vendor **MUST** hold and maintain ISO 13485 certification for the EMR offering as required by Health Canada’s medical device licensing requirements. The EMR vendor **MUST** submit a **valid** ISO 13485:2003 or ISO 13485:2016 Certificate along with the Application for EMR Certification.  | **[ ]**  |
| **B** | **Threat Risk Assessment(TRA) Summary including Risk Mitigation Plan** The EMR vendor **MUST** have an application level Threat Risk Assessment (TRA) completed on the EMR offering by an Information Security Professional with the appropriate credentials (e.g. CISSP: Certified Information Systems Security Professional). The EMR vendor **MUST** submit the TRA Summary and the Risk Mitigation Plan along with the Application for EMR Certification. The TRA Summary and Risk Mitigation Plan **MUST** reflect the EMR offering version that is being submitted for Certification.  | **[ ]**  |
| **C** | **Medical Claims Electronic Data TRANSFER (MC EDT) – Conformance Letter**The EMR vendor **MUST** provide a letter from the Ministry of Health and Long-Term Care stating that their EMR offering has successfully passed the conformance testing.The letter **MUST** reflect the EMR offering version that is being submitted for Certification. | **[ ]**  |
| **D** | **Health Card Validation (HCV) – Conformance Letter**The EMR vendor **MUST** provide a letter from the Ministry of Health and Long-Term Care stating that their EMR offering has successfully passed the conformance testing.The letter **MUST** reflect the EMR offering version that is being submitted for Certification. | **[ ]**  |
| **E** | **Drug Database License – Canadian Version**The EMR vendor **MUST** submit a valid license confirming that a Canadian drug database has been integrated in the EMR offering for prescribing medication, drug-to-drug and drug-to-allergy interaction. | **[ ]**  |
| **F** | **EMR Requirements Attestation** The EMR vendor **MUST** submit a fully completed **EMR Requirements Attestation Form** along with any documentation to support the Attestation. | **[ ]**  |

|  |  |  |
| --- | --- | --- |
| **G** | **EMR Hosting specification – substantiation REQUIREMENTS (Hosted EMR offerings only)**The EMR vendor **MUST** submit ALL documentation as stated in the **EMR Hosting Specification – Substantiation Requirements** document. | **[ ]**  |
| **H** | **Client Reference** The EMR vendor **MUST** submit documentation that provides advocacy from the domain for which this certification request applies; substantiation from clinical community supporting the Application for EMR certification. | **[ ]**  |
| **I** | **Commercial Labs – Conformance Letter(s)****Prerequisite for Stage 3**The EMR vendor **MUST** provide a letter certifying the interface with one or more commercial laboratories as stated in the Primary Care EMR Baseline Specification.The letter **MUST** be issued by the commercial lab and clearly identify the version of the EMR offering that was certified. This letter **MUST** be submitted to OntarioMD before validation activities for Stage 3 can begin. | **[ ]**  |