**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 13485 OR ISO 9001 Certificate**  The EMR vendor **MUST** submit a **valid** ISO 13485:2016 OR ISO 9001 Certificate along with the Application for EMR Certification.  EMR Vendors submitting the ISO 9001 Certificate will also need to provide an excerpt of the audited quality documentation (e.g., quality manual) that demonstrates the concept of patient safety (i.e., patients’ freedom from unacceptable risk) was included in the description of:   1. the needs and expectations of interested parties (ISO 9001:2015 Requirement 4.2) and 2. the scope of the quality management system (ISO 9001:2015 Requirement 4.3). |  |
| **B** | **Privacy Impact ASSessment (PIA) Summary including Risk Mitigation Plan**  The EMR vendor **MUST** have an application level Privacy Impact Assessment (PIA) completed on the EMR offering by an experience Privacy Specialist with the appropriate credentials (e.g. CIPP Certified Information Privacy Professional)  The EMR vendor **MUST** submit the PIA Summary and the Risk Mitigation Plan along with the Application for EMR Certification.  The PIA Summary and Risk Mitigation Plan **MUST** reflect the EMR offering version that is being submitted for Certification. |  |
| **C** | **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. |  |
| **D** | **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. |  |
| **E** | **BILLING INTEGRATION ATTESTATION**  The EMR vendor **MUST** submit an attestation that their EMR offering has successfully completed the jurisdiction specific integration.  The attestation **MUST** reflect the EMR offering version that is being submitted for Certification. |  |
| **F** | **Health Card Validation (HCV) ATTESTATION (ONTARIO ONLY)**  The EMR vendor **MUST** submit an attestation that their EMR offering has successfully completed the jurisdiction specific integration.  The attestation **MUST** reflect the EMR offering version that is being submitted for Certification. |  |
| **G** | **EMR Requirements Attestation**  The EMR vendor **MUST** submit a fully completed **EMR Requirements Attestation Form** along with any documentation to support the Attestation. |  |
| **H** | **EMR Hosting specification – substantiation REQUIREMENTS**  The EMR vendor **MUST** submit ALL documentation as stated in the **EMR Hosting Specification – Substantiation Requirements** document. |  |
| **I** | **Client Reference**  The EMR vendor **MUST** submit a reference letter from a current client substantiating the use of the EMR in a current clinical practice. |  |