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Applicant:		
Audited company:		
Lead auditor:		
Auditor(s):		
Type of Audit:		
Audit Dates:		

NOTE 1:
Write Nonconformity Reports in context of the requirements of ISO 13485/88; (not the Canadian MDR)

NOTE 2:
For CMDR, it is NOT the auditor's role to classify medical devices. Refer organization to Health Canada.

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<p><u>4.1 General requirements (4.2.1)</u></p> <p>Does the manufacturer have control over all outsourced processes and are these control mechanisms identified within the QMS?</p> <p><u>4.2.1 General (4.2.2) & CMDR [9] [10-20] [32]</u></p> <p>Does the manufacturer have files that contain, or refers to the location of the evidence of safety and effectiveness required in Sections 10 to 20? (e.g., records showing that essential requirements met in DMR, DHF, Technical File, etc.)</p> <p><u>4.2.2 Quality Manual (4.2.1) & CMDR [32(2)(f)]</u></p> <p>If the manufacturer excludes element 7.3 Design and Development from the scope of the QMS, does the quality manual contain a detailed justification of its exclusion based on CMDR Section 32(2)(f) allowable exclusion for Class II devices?</p>				

Notes

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<p><u>Quality Systems Certificates</u></p> <p>If TÜV issued a new or modified quality systems certificate did the manufacturer submit to Health Canada within 30 days?</p> <p><u>5.1 Management commitment (4.1)</u></p> <p>Does objective evidence exist of top management's commitment to meeting the requirements of the Canadian Medical Devices Regulations? (e.g. Device Licensing, Mandatory Problem Reports, Recalls etc.)</p> <p><u>5.6.2 Review input (4.1)</u></p> <p>Is a review of new or revised Canadian Medical Devices Regulations part of the input to management review?</p> <p><u>6.2.2 Competence, awareness and training (4.18)</u></p> <p>Have appropriate personnel been trained on relevant CMDR requirements? (e.g., internal auditors, regulatory affairs personnel, etc.)</p>				

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<p><u>6.3 Infrastructure (4.9)</u> & CMDR [14]</p> <p>Does the manufacturer have and maintain the necessary infrastructure to ensure that the characteristics and performance of their medical device(s) is(are) <u>not adversely affected</u> by <u>transport</u> or conditions of <u>storage</u>?</p> <p><u>7.2.1 Determination of requirements related to the product (4.3.2 + 4.4.4)</u> & CMDR [Part 1]</p> <p>Do <u>requirements</u> determined by the manufacturer <u>include</u> the appropriate parts of the <u>Canadian MDR</u> that apply to the medical device(s) that is (are) designed and manufactured under the control of the QMS?</p> <p>Have these <u>regulatory requirements</u> been documented <u>in</u> the <u>Quality Manual</u>?</p>				

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<p>Has the manufacturer used the Classification rules in Schedule 1 to appropriately classify any new devices?</p> <p>Is the manufacturer only selling licensed devices in Canada?</p> <p>If some of the MDR requirements have been delegated by the legal manufacturer to another area of the organization, has the delegation of responsibility been clearly defined and documented?</p> <p>If the manufacturer has delegated / permitted the importer to prepare and submit the information and documents with respect to the recall on the manufacturer's behalf was Health Canada notified in writing?</p> <p><u>7.3.2 Design and development inputs (4.4.4)</u> & CMDR [10-20]</p> <p>Has the manufacturer determined the design and development inputs related to the regulatory safety and effectiveness requirements?</p>				

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<p>Has the manufacturer determined the device licensing requirements for Class II, III or IV devices?</p> <p><u>7.3.6 Design and development validation (4.4.8)</u> & CMDR [12] [20] [32(3)(f) & (4)(1)]</p> <p>Has Design & Development validation been performed on initial production devices or their equivalents?</p> <p>Has the performance of any software used in the medical device been validated?</p> <p><u>7.3.6</u> & CMDR [34] [43(1)(b)] {13485:96 – 4.4.9}</p> <p>Does the manufacturer have a process or procedure for identifying a “significant change” to a Class III or IV device?</p>				

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<p>Does the manufacturer have a <u>procedure</u> for <u>amending</u> a Class III or IV medical device <u>license</u> in the event of a significant change to a device?</p> <p>Does the manufacturer <u>track changes</u> to the information and documents that had been supplied earlier to Health Canada but did not lead to a license amendment?</p> <p>Are these <u>changes reported</u> during the annual license renewal process required in section 43(1) (b)?</p> <p><u>Following</u> any design and development <u>changes</u>, is the <u>device master file</u> (technical file) <u>updated</u> ?</p> <p><u>7.4.1 Purchasing process (4.6.2)</u></p> <p>Do manufacturers who <u>use suppliers</u> to provide <u>finished devices</u> have documented procedures in place to ensure that the finished <u>device</u> is <u>safe</u> and <u>effective</u>?</p>				

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<p>Do manufacturers who use suppliers to provide parts, components or services that could affect the safety and effectiveness of the finished device have documented procedures in place to ensure that the finished device is safe and effective?</p> <p><u>7.4.2 Purchasing information (4.6.3)</u></p> <p>Has the manufacturer who purchases finished devices, parts, components or critical services like sterilization, described a required QMS that the supplier must be registered to?</p>				

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<p><u>7.5.3.1 Identification (4.8)</u> & CMDR [21]</p> <p>Do <u>device labels</u> contain:</p> <p>a) the <u>name</u> of the <u>device</u>;</p> <p>b) the <u>name</u> and <u>address</u> of the <u>manufacturer</u>;</p> <p>c) the <u>identifier</u> of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;</p> <p>d) in the case of a Class III or IV device, the <u>control number</u>;</p> <p><u>7.5.3.2 Traceability (4.8)</u> & CMDR [52-56] [66]</p> <p>Does the manufacturer and/or distributors have <u>records of distribution</u> of devices and are these records kept for the longer of, the projected useful life of the device as defined by the manufacturer, or two years after the device was shipped?</p>				

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<p>Do distribution records contain sufficient information to permit a complete and rapid withdrawal of a Class II, III or IV medical device from the market?</p> <p>If the manufacturer sells a device in Canada that is listed in Schedule 2 of the MDR, does the manufacturer have procedures and records that satisfy the traceability requirements of section 66?</p> <p><u>8.2.2 Internal audit (4.17)</u></p> <p>Do internal audits include requirements of both the Canadian Medical Device Regulations and ISO13485/88 ?</p>				

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<p><u>8.5.1 Improvement - General</u> <u>(4.1.3)</u> & CMDR [63-65]</p> <p>Does the manufacturer and his Canadian importer have documented <u>procedures</u> for them to:</p> <p>carry out an effective and timely <u>recall</u> of the device <u>following</u> a consumer <u>complaint</u> or reported <u>problem</u> related to device performance or safety;</p> <p><u>recall</u> or correct a device, or to <u>notify</u> its owners and <u>users</u> in <u>Canada</u> of its defectiveness or potential defectiveness after becoming aware that the device :</p> <p>a) may be <u>hazardous</u> to health;</p> <p>b) may <u>fail</u> to conform to any claim made by the manufacturer or importer relating to its <u>effectiveness, benefits, performance characteristics</u> or <u>safety</u>;</p> <p>or</p> <p>may <u>not meet</u> the requirements of the <u>Food and Drugs Act</u> (R.S., c. F-27, s.1) or the MDR (SOR/DORS/98-282)</p>				

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<p>8.5.1 CMDR [57(a)] [57(1)(b)]</p> <p>Does the manufacturer and its Canadian importer and distributors maintain records of reported problems or consumer complaints relating to the performance characteristics or safety of the device ?</p> <p>Are these problem reports or consumer complaints used as input into the corrective and preventive action system?</p> <p>Does the manufacturer and its Canadian importer have documented procedures to inform Health Canada of incidents that meet the mandatory reporting criteria found in Sections 59 to 62.</p>				

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