

IEC 62304, Ed. 1.1 - *Medical device software - Software life cycle processes*

- IEC 62304:06 +A1:15 CSV, ed. 1.1
 - A1:2015 is intended to add rqrts to deal with LEGACY SOFTWARE, where s/w dsgn is prior to existence of current version, to assist manufacturers who must show compliance to the standard to meet European Directives.
 - **Currently Can & EU are aligned with 62304, ed. 1.0, US allows either ed. 1.0 & 1.1**
 - **CENELEC has adopted EN62304:06 + A1:15 but not in OJEC as a Harmonized Standards under MDD**

Draft IEC 62304, Ed. 2.0 – *Health S/W – S/W Life cycle processes*

- Previous draft proj cancelled Nov 2014
 - Reason: change in scope of std & in comm. resources used (from QM focus to Health Informatics comm.)
- Draft project reactivated June 2016
- IEC work program CD level doc – Vote closes May 26, '17
 - Publication estimated Dec 2019
- Draft Scope (Comm rpt 62A/1185/CD): Applies to all s/w intended to be used for managing, maintaining or improving health of individual persons, or delivery of care. Defines rqrts for mfr's over entire life cycle including dsgn, mfr, installation, maintenance & disposal of health s/w