

Document Change History

Version	Description	Author	Date
A	Initial release	Gary Brennan	2016/10/10
B	Updated to newer template; Updated from Clause 1.8 to Clause 6.6 of Schedule 3; Updated Standards Applied list to include 14971 & DICOM and updated from 62366 to 62366-1; Updated Authorized signatory.	Megan Pellenz	2018-05-25
C	General maintenance, updated applied standards ISO 14971 to 2019 AM11:2021, added ISO 13485:2016, added A1:2013 to EN1041 and ISO 15223-1: 2021	Rob Berry	2022-09-014
D	Completed ISO 20417 standard review and replaced EN 1041 in accordance with SoTA, corrected QMS certificate information too	Rob Berry	2022-11-23