

Webinar on Harmonized Healthcare Standards

Tuesday 24 January 2023 (14:00 – 16:00)

Programme

14:00-14:05	Introduction & Practicalities (5 mins)	Els Somers (CEN-CENELEC)
14:05-14:10	Opening of the webinar and aim of the session (5 mins)	Sarah c Sim (SIS – Chair of ABHS)
14:10-14:25	HAS system and the role of the HAS consultants under the new contract (15 mins)	Federico Musso (European Commission, DG GROW/ H.3)
14:25-14:40	Specificities of MDR – IVDR – EC advice for a successful Annex ZA/ZZ OJEU citation (15 mins)	Mario Gabrielli Cossellu (European Commission, DG SANTE/ D.3)
14:40 – 14:50	Normative references in standards (10 mins)	Frédéric Mlanao – Compliance Account Manager (CEN-CENELEC)
14:50-15:00	Break (10 mins)	
15:00-15:10	The Harmonization procedure (10 mins)	Jennifer Ogbonna – Project Manager Healthcare (CEN-CENELEC)
15:10-15:30	Good Practices of Annex ZA (20 mins) EN ISO 14971:2019/A11:2021 and EN ISO 15223-1:2021	Jos van Vroonhoven, PhD, CStd - (CEN-CENELEC JTC 03) Lena Cordie-Bancroft (CEN-CENELEC JTC 03)
15:30 - 15:45	Good Practices of Annex ZA (15 mins) CEN/TC 204 'Sterilization of medical devices' - EN ISO 14160:2021	Eamonn Hoxey Ph D, B Pharm, F R Pharm S (CEN/TC 204)
15:45-15:55	Key points (10 mins)	Jennifer Ogbonna (CEN-CENELEC)
16:00	Conclusion & closing (5 mins)	Sarah c Sim (SIS – Chair of ABHS)