Medical Device Regulatory Convergence Project (MDRC)
Kenyan Bureau of Standards, Pharmacy and Poisons Board and
Medical Technology Industry Association of Kenya (MEDAK)

Workshop on Conformity Assessment, Product Imports & International Standards

Date: 10 November 2023
Time: 9:00 – 16:45 Nairobi, Kenya (2:00 – 9:45 AM ET)
Language: English
Format: Hybrid. In-person at Radisson Blu Upper Hill Hotel, Mt Elgon Room
For in-person and virtual participation, please register here.

Institutional Representatives

Kenya Bureau of Standards (KEBS)	Pharmacy and Poisons Board (PPB)	African Organization for Standardisation (ARSO)	MEDAK
Esther Ngari	Paulyne Wairimu	Charles Gachahi	Steve Kipkoti
Leinad Mwendwa	Ali Arale	Sandra Umugwaneza	Mercy Njuguna
Tobias Ololoo	Eric Kitangala	Emmanuel Kirwa	
Titus Oyoo	Shellan Omondi		
	Maureen Njiru		

Time	Topic
8:30 – 9:00	**Participants Registration**
9:00 – 9:10	**Welcome and Opening Remarks** • Sandra Ligia González, Medical Devices Lead – MDRC • Daniel Vázquez, Sr. Standards Specialist & Textile and Apparel Industry Lead, U.S. Agency for international Development – USAID • Leslie McDermott, American National Standards Institute - USAID • Kenyan Bureau of Standards – KEBS • Pharmacy and Poisons Board – PPB • Steve Kipkoti, Medtronic – MEDAK
9:10 – 9:15	**Workshop Objectives** Marina Carvalho – MDRC
9:15 - 10:00	**Conformity Assessment Process for Medical Devices in Kenya** Leinad Mwendwa, PVoC Officer, KEBS
10:00 – 10:20	**PPB - Role in relation to PVoC** Paulyne Wairimu, TBC
10:20 – 10:35	**Morning Tea Break**

10:35 – 12:30	**PVoC - Open discussion on challenges & opportunities (Continuation)** Moderator: Marina Carvalho – MDRC Kenya Bureau of Standards – KEBS Pharmacy and Poisons Board – PPB Medical Technology Industry Association of Kenya – MEDAK **Conclusions and group proposal for next steps**
12:30 – 13:30	**Lunch**
13:30 – 14:40	**International Standards. The Role of National & Regional Standards Development Organizations & Essential Standards for Medical Devices and IVDs** Scott Colburn / Terry Woods, USFDA: CDRH/OST – Standards and Conformity Assessment Program (SCAP) Titus Oyoo, Director of Standards – KEBS Sandra Umugwaneza, African Organization for Standardisation – ARSO Q&A 30 min
14:40 – 15:00	**Afternoon Tea Break**
15:00 – 16:30	**Conformity Assessment - IECEE CB Scheme. The Whats and the Hows** Steve T. Margis, IECEE Chair | IEC CAB | USNC/IECEE Vice Chair | UL Solutions Director Conformity Assessment, Virtual Q&A 30 min
16:30 – 16:45	**Closing Remarks** Kenya Bureau of Standards – KEBS Pharmacy and Poisons Board – PPB Medical Technology Industry Association of Kenya – MEDAK Sandra Ligia González – MDRC