- Hello, all. My name is Elisabeth George and I am here representing the medical device industry. I am the Head of Global Regulations and Standards for Philips. I'd first like to thank the host of today's event for this opportunity to speak on this panel. I would also like to thank my colleagues for their engagement on this panel and all the stakeholders participating. I am so excited to be here today with this talented group of people to share our perspectives on conformity assessment

- Philips is an active member of many trade associations globally including **Global Diagnostic Imaging, Healthcare IT & Radiation Therapy** (DITTA) and **Global Medical Technology Alliance** (GMTA), both trade associations of trade associations, as well as many regional organizations in many countries like Brazil, Canada, Mexico .

- We are also active members of many standards developing organizations including ISO, IEC, CTA, AAMI, NEMA, ASTM and many more. We embrace the use of international standards to ensure patient safety and compliance globally. Our membership in the **American National Standards Institute** (ANSI) permits our US employees to fully engage in the international standardization of medical technology.

- We also participate in **International Medical Device Regulators Forum** (IMDRF) via Stakeholder Meetings and support development of workshops through DITTA and GMTA. This engagement affords us the opportunity to engage with 10 member jurisdictions regulators as well as to meet with industry representatives from around the world. Philips also supports the work of our **Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector** which brings together 27 medtech associations across the Western Hemisphere to accelerate regulatory convergence for our industry as well as the **Global Harmonization Working Party** which brings together more than 30 jurisdictions of regulatory and industry members.

- As you can see, we are very busy. Today I will share examples of how conformity assessment constructively supports the medtech sector, health & wellness as well as the economic value.

- I think it's important to clarify what medical technology is. It is essentially anything and everything you might see at a hospital, clinic or point of care that is not drugs and not the personnel.

- This can range from things such as Advanced Molecular Imaging, Computed Tomography Machines, Ventilators, Defibrillators & Patient Monitors as well as SW solutions and the associated services like those that Philips manufactures, to other types of diagnostics, implants such as coronary stents, orthopedics such as artificial hips, 3D printers of replacement human tissues and even low risk products such as band-aids and tongue depressors.

- Many medical technologies are now globally recognized from their front-line role in combating COVID-19, from personal protective equipment (PPE), ventilators, and diagnostic kits to the range of broader technologies to identify and treat coronavirus.

- It should be noted that for non-medtech audiences, another piece of medical technology can even be your smart phone which is made up of hundreds of thousands of components that change every 12-18 months. You've all seen the apps that you can download from the app store and faced the continuous updates to ensure everything works.

- Like almost everything these day, the medical device supply chain is global. There is no single country that does or can manufacture any single medical device including all the components. Our goal as industry is to be as innovative as we can be in designing, manufacturing and delivering new technologies that save and improve the lives of patients everywhere, and to do this – we seek to remove unnecessary obstacles between these life-saving technologies and patients.

- At events like this one, it is important to acknowledge and attempt to address the technical barriers to trade, the majority of which derive from the lack of having a formalized, consistent, comprehensive Good Regulatory Practice Policy. It's important to have implementation of the World Trade Organization Technical Barriers to Trade Agreement so as not to have regulatory mis-alignment. This can impact the time to market as well as even potentially access to key innovations.

- So it is for this reason that we support trade packages that address
    - Customs and Trade Facilitation including mutual recognitions through standards and conformity assessment,
    - Good Regulatory Practices that are aligned and embrace standards
    - International alignment of technical regulations, standards and conformity assessment are key in supporting access to medtech solutions. These practices support cost effective, timely access to the most innovative solutions.

- For example, if Philips designs a new product. We start by utilizing internationally recognized standards in our development. We then execute the required inspection and tests per the associated standards test requirements in our test labs under the oversite of organizations like Intertek or UL. We then want to sell our products globally to support clinical needs that are global. Our design and manufacturing sites are located around the world and all are managed under certified quality management systems and appropriate site registrations per the requirements of country they are located in as well as the countries we plan to sell into. For Philips we have more than 75 locations around the world where we design and/or manufacturer our products.

- For example, for both US (FDA) and EU (NB/Competent Authorities), we are expected to prove our conformance to mandatory and/or voluntary standards. We either attest to this via a declaration of conformity (and use FDA's ASCA Program) or we submit test data/reports as a part of our submissions. It is important that the manufacturer works closely with their regulators either directly via a pre-submission type meeting or indirectly via trade associations or organizations like IMDRF/GHWP. Regulators who participate in standard development support future planning for the use of standards in their regulatory strategy. These venues permit opportunity for sharing of challenges and best practices. Key element to note – **SAME TEST DATA AND CERTIFICATIONS ARE USED IN BOTH REGIONS.** We look forward to this be truly global as processes like the IMDRF Medical Device Single Review Program (MDSRP) becomes a reality.

- In some regions (like Brazil, China, Japan), we face technical regulation with conformity assessment requirements that are not globally aligned. For our sector, each jurisdiction (country) has their own regulators. (e.g.; US – FDA, Brazil – ANVISA, China – NMPA). Each jurisdiction significantly varies in their structure and experience levels. The FDA has been actively engaged in the review and approval of medical devices since 1976 while NMPA was 1998 and ANVISA was created in 1999. We also note that the resource levels vary significantly including specifically their ability to perform inspections, focus on testing and their level of engagement in standard development including development of Standardized Test Report Forms (TRF's). These variations in structure, resources and standards recognition are also evident in their requirements for re-testing, re-certification and additional labeling being time-based rather than solely innovative change based.

- I'd also like to mention that within the EU, we also face technical regulation challenges with conformity assessment requirements that are not globally aligned since they ONLY recognize ENs and not the international standards and ENs are only linked to ISO and IEC and not any other WTO TBT conforming standards organizations.

- We were pleased to see open discussion across many jurisdictions on leveraging best practices including mutual recognition of testing to global standards. The value in alignment and recognition of Conformity Assessment Bodies globally under the International Laboratory Accreditation Cooperation (ILAC) is we will TEST ONCE and submit same data to all jurisdiction which is step one to supporting faster to market permitting all patients globally access to the same care. Step two will be a true single review program – TEST ONCE SUBMIT ONCE RECOGNIZED GLOBALLY.

- So in closing, as a medical device industry representative our desire is to ensure access to all high quality, reliable, compliant solutions in a timely manner and the best way to do that is utilizing international standards and conformity assessment schemes that are globally recognized.