

WHO Medical Devices

Newsletter April 2024

WHO Campaign on Medical Devices

In this issue you will find: information from the 77th World Health Assembly, the registration link to the WHO National Oxygen Scale-up framework meeting, a reminder for the fifth WHO model list of essential in vitro diagnostics (EDL 5), and open applications for prequalification of blood glucometers to manage diabetes.



Seventy-seventh World Health Assembly

27 May to 1 June 2024

The Seventy-seventh World Health Assembly is being held in Geneva, Switzerland, on 27 May – 1 June 2024. The theme of this year's Health Assembly is: All for Health, Health for All. Main topics include Pandemic prevention, preparedness and response; as well as amendments to the International Health Regulations, both of outmost global importance.

Proceedings will be webcast live from <u>this web page</u>. Simultaneous interpretation will be available in Arabic, Chinese, English, French, Russian and Spanish.



WHO National Oxygen Scaleup Framework Meeting

Oxygen is an essential medicine, requiring medical devices to deliver to patient and to monitor. The COVID-19 called us to the attention that it should be available for emergencies, pandemics but also for surgery, and critical care, COPD among multiple other uses.

Almost a year ago, WHA76.3 Resolution
"Increasing access to medical oxygen" was
approved by the World Health Assembly.
Now countries will work on an access
roadmap and the 14-16 May meeting can be
accessed online.

Registration



Reminder - We are glad to share with you the call for submissions for the fifth WHO model list of essential in vitro diagnostics (EDL 5)

The call is open until 30 June 2024, 12PM CEST

The EDL is a health policy document, based on scientific evidence, consisting of a list of categories of IVD tests and recommendations for using those tests in relation to the assay format, test purpose, specimen type and health care setting. The EDL aims to serve as a reference to guide development of or to update a national EDL (NEDL) at the country level within the framework of universal health coverage.

The call is open to all stakeholders so please check all the details in the <u>announcement</u> and help us share it among your networks. Let's make of this call an opportunity to contribute to the efforts towards greater availability and better access to IVD testing for all.

More information



WHO announces expansion of prequalification of in vitro diagnostics to include

diabetes

WHO is proud to announce the expansion in the prequalification (PQ) scope of in vitro diagnostics (IVDs). Applications for PQ can include in vitro diagnostic medical devices for monitoring of blood glucose in capillary blood and HbA1c point-of-care assays. This marks an important milestone for the Global Diabetes Compact and the public health response to the rapidly evolving epidemiology of noncommunicable diseases. Importantly, it stresses the importance of ensuring and accelerating access to good quality health

products for people with diabetes.

Manufacturers interested in undergoing a prequalification assessment for these products are invited to consult the WHO website to access the technical specifications and contact the in vitro diagnostics assessment team at diagnostics@who.int to schedule a presubmission meeting. Prequalification applications will be accepted by end of Q1 2024 and a webinar for manufacturers will be scheduled soon to introduce the prequalification specifications and the assessment process. More information on the upcoming events will be provided soon.



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