힘내라 대한민국	Press Release	Date	November 4(THU) 2020
		Division	High-Tech Medical Devices (Digital Health Devices TF) In Vitro Diagnostic Devices
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An Introduction of Korean Regulations on Digital Medical Device to the International Community

A Publication of 4 types of Approval/Review Standards (Guideline) on Digital Therapeutics, etc. in English

☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) published 4 types of Approval/Review Guidelines in English to actively promote Korean regulations on Digital Therapeutics (DTx), AI medical devices, etc., which are considered as the main technology in non-face-to-face era, to the international community.

√ **Digital Therapeutics (DTx):** Software as a medical device (SaMD) used for the prevention/care/treatment of diseases based on scientific and clinical evidence on the treatment mechanism

√ **Software as a Medical Device (SaMD):** The medical device which consists of independent software system that is appropriate for the use of medical devices without any dependency on hardware

○ The English version guideline is published with the aim of introducing preemptively prepared regulations on digital medical devices to foreign regulatory authorities including the US FDA and the related foreign industries, and supporting Korean businesses to explore channels for export.

☐ The 4 types of guidelines in English include ▲an approval/review guideline for DTx ▲an approval/review guideline for medical devices using Big Data and AI technology, ▲an approval/review guideline for the

cyber security of medical devices, and ▲an approval/review guideline for the in vitro diagnostic medical devices (IVDs) for the COVID-19.

○ The MFDS proposed the world's first approval standard on functions and clinical trials of AI medical devices (Nov. 2017) and DTx (Aug. 2020), thereby publishing 2 types of related guidelines in Korean.

○ In particular, "An approval/review guideline for AI medical devices" has been recognized its excellence from foreign regulatory authorities including the US and European Union. On June 25, Korea became the first chair of the AI medical device working group at the "International Medical Device Regulators Forum (IMDRF)."

* IMDRF (International Medical Device Regulators Forum): A consultative body of 10 regulatory authorities including the US and the EU who lead the global harmonization of regulations on medical devices. Korea joined the IMDRF in December, 2017.

○ In addition, the MFDS prepared (on April 24) a guideline for the performance standard and technical documentation method needed for the official approval of the IVDs for the COVID-19 for the first time in the world. Until now, 5 domestically manufactured products have been officially approved.

□ The MFDS stated that it hopes the publication of English guidelines be an opportunity to promote the excellence of Korean regulations on medical devices. Also, the Ministry added that it will further actively support domestic medical device industry to enhance the global competitiveness and expand the exports.

※ Online Distribution of Approval/Review Guidelines

✓ The MFDS official webpage (in English) (www.mfds.go.kr/eng) > Medical Devices > Regulations

✓ The MFDS official webpage (in Korean) (www.mfds.go.kr) > Regulations/Data > Data Center > Manual/Guideline