VUNO obtains CE mark for 5 medical AI solutions

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South Korea based medical artificial intelligence (AI) solution development company VUNO Inc. and a member company of the Born2Global Centre, gained the Class IIa CE markings for five of their AI solutions.

The five CE marked solutions are: VUNO Med®-BoneAge™, VUNO Med®-DeepBrain™, VUNO Med®-Chest X-Ray™, VUNO Med®-Fundus AI™, and VUNO Med®-LungCT AI™.

These products can now be commercialized and sold in 27 member states of the European Union, the Acceding countries as well as EFTA states (Iceland, Liechtenstein, Norway and Switzerland).

They can also make inroads into countries that recognize the European CE mark such as those in the Middle East, Asia, South and Central America, and Africa.

VUNO was assessed and deemed to meet EU safety and health protection requirements by a Notified Body based on a more stringent clinical validation standards and medical device guidelines.

The efficacy and safety of those products demonstrated by a series of clinical research results and papers published in high impact journals and prestigious international seminars were of great help to satisfy the strict requirements.

Of the five MFDS (Ministry of Food and Drug Safety) approved products, four products (VUNO Med®-Fundus AI™, VUNO Med®-Chest X-ray™, and VUNO Med® - BoneAge™ and VUNO Med® Lung CT AI™) received regulatory approval based on the proven effectiveness of performance through clinical trials.

With such a robust portfolio, it is anticipated that VUNO Med solutions are to be used as key diagnostic supporting tools across many different medical environments overseas.