MEDIKORS Inc.

# EC Declaration of Conformity

**Manufacturer : MEDIKORS Inc.**

HQ Address : #F410, Seongnam CenterM, 33 Sagimakgol-ro 62 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

Factory Address : #F412, #F413 Seongnam CenterM, 33 Sagimakgol-ro 62 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea

**European representative :** JaviTech e.K.
Sachsenhausener Straße 16, 65824 Schwalbach am Taunus, Germany

**Product : X-Ray Bone Densitometer**

**Model : InAlyzer AIR**

**GMDN CODE : 37661**

**Classification : ClassⅡb by Rule 10 of Annex IX, MDD 93/42/EEC as amended by Directive 2007/47/EC**

**Conformity Assessment Route : AnnexⅡ, MDD 93/42/EEC as amended by Directive 2007/47/EC**

We hereby declare that the complies with the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex Ⅱ as the conformity assessment.

**Applied Standard**

| | | |
|---|---|---|
| EN ISO 14971:2019 | EN 60601-1-3:2008+A11:2016 | EN 61000-3-2:2014 |
| EN ISO 20417:2021 | EN 60601-1-6:2010+A1:2013 | EN 61000-3-3:2013 |
| EN ISO 15223-1:2021 | IEC 60601-2-28:2017 | MEDDEV 2.7/1 rev.4 |
| EN ISO 13485:2016 | EN 62304:2006+A1:2015 | MEDDEV 2.12/2 rev.2 |
| EN 60601-1:2006+A1:2013 | EN 62366-1:2015+A1:2020 | MEDDEV 2.12/1 rev.8 |
| EN 60601-1-2:2015 | EN 55011:2009+A1:2010 | |

**CE making starting date :** 2019.12.18

**CE making expiration date** : 2024.05.26

**EC certificate number :** 2195-MED-1935201

**NB :** Szutest Uygunluk Değerlendirme A.Ş. / Address: Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul, Turkey

**Date of issue: 2024.05.11**

**Signature:**

**President of MEDIKORS Inc.**