EC Declaration of Conformity

We,
Manufacturer Name: **Winnoz Technology, Inc.**
Address: 5F.-1 No.238, Liancheng Rd., Zhonghe Dist., New Taipei City 235, Taiwan

System Name	**Model Number**
"Haiim" Vacuum-assisted blood collection system	WH-001
Product Name	
"Haiim" Vacuum-assisted blood collection system Main Device	HD-001
"Haiim" Vacuum-assisted blood collection system Cassette (Non-sterile)	HC-001

as the Manufacturer of

Classification: Others
Conformity assessment: IVDD 98/79/EC Annex III

Here with declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

- EN ISO 13485:2016
- EN ISO 14971:2019
- EN 60601-1:2013
- EN 60601-1-2:2015
- EN ISO 10993-5:2009
- EN ISO 10993-10:2002
- EN ISO 15233-1:2016
- EN ISO 17664:2017
- IEC 60601-1-6:2010+AMD1:2013
- IEC 62366:2007+A1:2014
- IEC 62304:2006+A1:2015

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

Le-Chang Hsiung

Le-Chang Hsiung, CEO

2020-09-09, New Taipei City, Taiwan
Date, Place