Winnoz

EC Declaration of Conformity

Manufacturer Name: **Winnoz Technology, Inc.**
SRN: Not available
Address: 5F.-1 No.238, Liancheng Rd., Zhonghe Dist., New Taipei City 235038, Taiwan

Products:

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
"Haiim" Vacuum-assisted blood collection system Cassette-L (Non-sterile)	HC-002

Analyte: Not applicable (sample collection device)

Basic UDI-DI: 471988964WH-001LQ
Classification according to Annex VIII of the Regulation (EU) 2017/746: A according to Rule 5(b)

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, which apply to it.

Conformity assessment procedure: Annex II and III

EDMA code: 29 01 10 01

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
- EN 13612:2002

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
SRN of the Authorized Representative: **DE-AR-000000002**

Le-Chang Hsiung

Le-Chang Hsiung, CEO

2022-07-19, New Taipei City, Taiwan
Date (YYYY-MM-DD), Place