



TO WHOM IT MAY CONCERN

CLARIFICATION LETTER

The medical devices classified as Class II, have notified body CE Certificate issued by third party. These devices are;

- Blood Bank Refrigerator: EKN25 , EKN50, EKN100, EKN200, EKN300, EKN600, EKN25 VK , EKN50 VK, EKN100 VK, EKN200 VK, EKN300 VK, EKN600 VK
- Thrombocyte Incubator: ECI-1, ECI-2, ECI-2, ECI-1 VK, ECI-2 VK, ECI-3 VK
- Thrombocyte Agitator: EAJ05, EAJ09, EAJ-L09
- Blood Plasma Freezer: EE100, EE150, EE300, EE600, EF100, EF150, EF300, EF600, EE100 VK, EE150 VK, EE300 VK, EE600 VK, EF100 VK, EF150 VK, EF300 VK, EF600 VK

Attachment 1; CE certificate issued by SZUTEST

However, the Laboratory Refrigerators classified as Class I, have only CE declaration of conformity issued by manufacturer, Class I Devices cannot have the CE Certificate approved by third parties. These devices are;

- Ultra Low Freezer: YULT400 , ULT200 , ULT470 , ULT730
- Laboratory & Pharmacy Refrigerator: EKT80, EKT-A80, EKT150, EKT160, EKT-A100 , EKT175, EKT-A175, EKT425 , EKT-A425, EKT725 , EKT-A725, EKT 1450 , EKT-A 1450,
- Refrigerator with Two Section: Fridge + Freezer: EKT-D 175, EKT-D 425, EKT-D 500.

Attachment 2; CE Declaration of Conformity issued by Manufacturer EMSAS A.S.

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