



TO WHOM IT MAY CONCERN

August 19th , 2022

CLARIFICATION LETTER

The medical devices classified as Class 2, could have only CE Certificate. 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

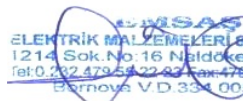
Attachment 1; CE certificate issued by SZUTEST

However, the medical devices classified as Class 1, do not have the CE Certificate approved by third parties. As manufacturer's declaration, CE Declaration of Conformity can be provided in accordance with CE directives. These devices are;

- Ultra Low Freezer: YULT400 , ULT200 , ULT470 , ULT730
- Laboratory & Pharmacy Refrigerator: EKT80, EKT150, EKT175, EKT250, EKT425 , EKT725 , EKT 1450 ,
- Laboratory Oven-Etuve: ET150
- Water Bath: ESB10

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

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