



DECLARATION of CONFORMITY

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We declare that following product are in accordance with **93/42/EEC Medical Device Directive (and 2007/47/EC amendment) ANNEX V, 2006/42/EC Machinery Directive, 2014/30/EU Electromagnetic Compatibility Directive and applicable standards.**

PRODUCT NAME : EE 150 , EE 300 , EF 150 , EF300 Plasma Freezer
EKN 25 , EKN 50 , EKN 100 , EKN 200 , EKN300 , EKN600 Blood Bank Refrigerator
ECI1 , ECI2 , ECI3 Incubator , EAJ05 , EAJ09 , EAJL09 Agitator ,
EPS10 Plazma Thawer,EMI50 , EMI150 , EMI350,EMI-D 500 Warming Cabinet

CLASS : IIa

RULE : 2 (According to Annex IX, 93/42/EEC)

APPLICABLE STANDARDS:

TS EN 980:2008	TS EN ISO 15223-1:2016
TS EN ISO 14971:2016	TS EN 1041:2014
TS EN 62366:2016	TS EN 62366-1:2016
TS EN 61010 -1:2012	TS EN 60027-1:2010
TS EN 60601-1,	TS IEC 60601-1
TS IEC 60227-6:2003	TS IEC 60245-7:2007
TS EN 61326-1:2013	TS EN 61000-4-2:2014
TS EN 61000-4-4:2013	TS EN 61000-4-5:2014
TS EN 61000-4-6:2014	TS EN 61000-4-8:2010
TS EN 61000-4-11:2006	TS EN ISO 10993 – 1:2014

GMDN NR.: 35704- Freezer, blood product

NOTIFIED BODY: SZUTEST Teknik Kontrol ve Belgelendirme Hizmetleri Tic. Ltd. Şti. ,Yukarı dudullu Mah. NATO Yolu Cad. Çam Sokak No: 7 Ümraniye – İSTANBUL

EC CERTIFICATE NO: : 2195-MED-1732001
EC CERTIFICATE DATE: : 16.11.2017
NB NO : 2195
SERİ NO : Started with xxxx
CE Marking Start :
MANISA / TURKEY Date 16.11.2017

This declaration is valid for all manufactured CE-marked products from the date of issue until the issue of another declaration or cancellation of this declaration.

Sinem VARDAR
Deputy General
Manager

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