

DECLARATION OF CONFORMITY

Manufacturer: Safetran BioMedical Inc.
3F., No. 1, Alley 16, Lane 120, Lide Road, Beitou Dist., Taipei City 11259,
Taiwan R.O.C.

European Authorized representative: MEDICA S.P.A.
VIA DEGLI ARTIGIANI, 7 41036 MEDOLLA MODENA - ITALY

Declare under our sole responsibility that the product

Blood components apheresis machine

93/42/EEC Annex IX rule 11, Class IIa

Produced in model. Q1, Q2

to which this declaration relates is in conformity with the following the provisions of
Directive

MDD 93/42/EEC according to 2007/47/EC,

Article3(Annex I), Annex II Item 4 excluded

And following standards

EN 980:2008	EN 1041:2008	EN ISO 13485:1012/AC:2012	EN 62366:2008
EN61010-1:2010	EN 61010-2-20:2016	EN 62304:2006	EN ISO 14971:2012
EN 61326-1:2013	EN 61326-6:2013		

under the supervision of notify body number 0120, SGS United Kingdom Ltd Systems&
Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

Safetran BioMedical Inc.

Registration No.:

Place	Date	Management Representative
Taipei, Taiwan,	2017.07.28	

