EC Declaration of Conformity

Manufacturer:

Zhengyuan Technology co., Ltd.
A-7 Floor, Huajing Business Square, No.20,
South Fenghui Road, Xi'an, Shaanxi,
710075 China

We, the manufacturer, herewith declare that the products:

REF:2151/2101/2102/2103/2104/2105/2106/2107/2108/2109/2110/2111/2112/2118/2119/2125/2126/2128/2129/2201/2202/2203/2205/2206/2207/2208/2209/2210/2211/2212/2213/2214/2215/2216/2301/2302/2304/2305/2306/2308/2309/2310/2311/2312/2313/2314/2315/2316/2317/2318/2401/2402/2404/2406/2407/2408/2409/2410/2411/2412/2413/2414/2416/2417/2418/2419/2420/2422/2423/2424/2425/2426/2427/2428/2429/2430/2431/2432/2433/2434/2435/2436/2437/2438/2439

meet the provisions of Directive 93/42/EEC which apply to them.

The classification and criteria of the medical device:

Product Name	Part no.	Classification	Criteria
Plasma Separators For Single Use	2201/2203/2204/2205/2207/2210/2211/2212/2213/2214/2301/2302/2304/2305/2306/2308/2309/2310/2311/2312/2313/2314/2315/2316/2317/2318/2401/2402/2404/2406/2407/2408/2409/2410/2411/2412/2413/2414/2416/2417/2418/2419/2420/2422/2423/2424/2425/2426/2427/2428/2429/2430/2431/2432/2433/2434/2435/2436/2437/2438/2439	IIb	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIb , rule18.
Plasma Separators For Single Use	2202/2206/2208/2209/2215/2216	IIa	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIa , rule 6.
Centrifugal Blood Processing Bowl for Single Use	2101	IIb	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIb , rule 3.

Apheresis Tubing Set for Single Use	2102/2105/2113/2128/2129	IIa	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIa , rule 2
Plasma Collection Bag for Single Use	2103/2106/2107/2108/2109/2110/2111/2114/2119	IIb	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIb , rule 18.
Apheresis Needle Assembly for Single Use	2104/2112	IIa	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIa , rule 6.
Plasma Collection Bottle for Single Use	2125/2126	IIb	According to the MDD 93/42/EEC, Annex IX Classification Criteria, It's in Class IIb , rule18.

CE 0197

The product concerned has been manufactured under a quality management system according to Annex Ⅱ of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60093044 0001
Issue date: 14.04.2014
Expiry date: 13.04.2019

following the procedure relating to the EC Declaration of Conformity set out in Annex Ⅱ of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Zhengyuan Technology Co., Ltd.

Address: A-7 Floor, Huajing Business Square, No. 20, South Fenghui Road, Xi'an, Shaanxi, 710075 China

2016-1-20 Xi'an — General Manager: Li Wenhui

Li wen Hui

Place, date — *Legally binding signature, Function*