

# Shandong Qinkai Medical Industry Co.,Ltd.

(South Section of Quancheng Road in Industrial Park) ,Medical  
Equipment Industrial Park,Chengwu County,Heze,274200  
Shandong,P.R.China

## EC DECLARATION OF CONFORMITY

Manufacturer's Name: :Shandong Qinkai Medical Industry Co.,Ltd.  
Manufacturer's Address: :(South Section of Quancheng Road in Industrial Park) ,Medical  
Equipment Industrial Park,Chengwu County,Heze,274200  
Shandong,P.R.China

Name of Device : Disposable Blood Transfusion Sets  
Classification : Class IIa  
Conformity Assessment Procedure : EC Declaration of conformity set out in Annex V  
Conformity Route : Self Declaration

**We herewith declare that the above mentioned products meet the provisions of the council  
Directive 93/42/EEC for medical devices.All supporting documentation is retained under the  
promises of manufacturer**

Quality Management System : EN ISO 13485:2012 + AC:2012  
Notified Body Name/Address : TUV Rheinland LGA Products GmbH  
Tillystraße 2 – 90431 Nurnberg  
Registration No :DD 2319673-1  
Registration Date :2021-04-23  
Cert valid Until :2024-05-26  
Issue Date :2021-04-23  
Stamp /signature :

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