

EC DECLARATION OF CONFORMITY



**Manufacturer
Address**

Manufacturer: Changsha Renji Medical Equipments Co.,Ltd.

Post Add: Building B8, Changsha E Center, No.18 Xiangtai Road,
Liuyang Jingkai District, Changsha City, Hunan
Province, China. 410300

**European
Representative**

Authorized Representative Name: Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

**Product
Information**

Product Name: Blood Collection Tube & Vacuum Blood
Collection Tube
No Additive, Clot Activator, Gel & Clot Activator, EDTA+NaF
Lithium Heparin, Sodium Heparin, K2EDTA, K3EDTA,
Na2EDTA, Sodium Citrate, ESR
Specification: 100T/Box, 1200T/Carton

Classification

Others

**Conformity
Assessment
Route: Annex III**

*We, Changsha Renji Medical Equipments Co.,Ltd, under our sole
responsibility declare that the above-mentioned products meet
the provisions of the following EC Council Directives and
Standards. All supporting documentations are retained under the
premises of the manufacturer.*

In vitro diagnostic medical devices directive:

**General
Applicable
Directives**

*DIRECTIVE 98/79/EC OF THE EUROPEAN PARLLAMENT AND OF
THE COUNCIL OF 27 October 1998 on in vitro diagnostic medical
devices.*

Standards Applied

EN 13612:2002/AC:2002 EN ISO 13485:2016
EN ISO 14971: 2012 EN ISO 23640:2015
EN ISO 18113-1: 2011 EN ISO 18113-2:2011
EN ISO 15223-1: 2016 EN 13641: 2002

Address: Changsha City, Hunan Province, China.
Date: Nov 8, 2021

Name: Li Renjiang
Position: Managing Director

Signature:

