EC DECLARATION OF CONFORMITY

CE

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.*
General Applicable Directives	*In vitro diagnostic medical devices directive: 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 14971: 2012 EN ISO 18113-1: 2011 EN ISO 15223-1: 2016 EN ISO 13485:2016 EN ISO 23640:2015 EN ISO 18113-2: 2011 EN 13641: 2002

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

Name: Li Renjiang
Position: Managing Director

CHANGSHA RENJI MEDICAL EQUIPMENT CO.,LTD.

Signature: Li Renjiang

Digitally signed by Chirtoacă Iurie
Date: 2022.09.10 17:14:22 EEST
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