# EC DECLARATION OF CONFORMITY

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| **Manufacturer Address** | Manufacturer: Changsha Renji Medical Equipments Co.,Ltd.<br>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.<br>Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. |
| **Product Information** | Product Name: Blood Collection Tube &Vacuum Blood Collection Tube<br>No Additive, Clot Activator, Gel & Clot Activator, EDTA+NaF Lithium Heparin, Sodium Heparin, K2EDTA, K3EDTA, Na2EDTA, Sodium Citrate, ESR<br>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<br>EN ISO 14971: 2012<br>EN ISO 18113-1: 2011<br>EN ISO 15223-1: 2016<br>EN ISO 13485:2016<br>EN ISO 23640:2015<br>EN ISO 18113-2: 2011<br>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
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