Manufacturer: Beijing He Kang Jin Dian Technology Development Co., Ltd., 3rd Floor, Building 7, No.15 Juyuanzhong Road, Mapo, 101399 Shunyi District, Beijing, People's Republic of China

EC REP SHANGHAI INTERNATIONAL HOLDING CORP. GMBH(EUROPE)

EIFFESTRASSE 80,20537 HAMBURG GERMANY

Medical Device: **Platelet Rich Plasma of Extraction Vacuum Blood Collection Tube, 1ml、2ml、3ml、4ml、5ml、6ml、7ml、8ml、10ml、12ml、20ml、30ml、40ml、50ml;**

Classification - Annex IX: **class IIA, rule 3**

Conformity assessment Route: **Annex ii.3 excluding（4）**

We, Beijing He Kang Jin Dian Technology Development Co., Ltd., herewith declare that the stated medical devices

meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 june 1993 concerning medical devices;

including, at 21 march 2010, the amendments by Council Directive 2007/47/EEC.

All supporting documentation is retained at the premises of the manufacturer.

We, Beijing He Kang Jin Dian Technology Development Co., Ltd., is exclusively responsible for the DoC.

Standards applied:

EN556-1:2006, EN 1041:2008, EN ISO10993-1:2009+A1:2010, EN ISO10993-5:2009, ISO10993-10:2010, ENISO 11137-1:2006, ENISO11737- 1:2006/AC:2009, ENISO11737- 2:2009, EN ISO13485:2016, EN14820:2004, EN ISO14971:2012, EN ISO15223-1:2016.

Notified Body: **TÜV SÜD Product service GmbH**
Ridlerstr 65, 80339 München, Germany

identification number CE 0123

(EC) Certificate(s): No. G1 102900 0002 Rev.00

Start of CE-marking: None

Place, Date of Declaration: **Beijing, 15 - February - 2022**

Signature:

name: Mr. Bin Huang

POSITION: MANAGER

EXP.DATE: 26-May-2024