CERTIFICATE

# EC Certificate

## Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

**Certificate Number: 1984-MDD-18-530**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

**KANSUK LABORATUARI SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Yassıören Mahallesi Fırat Sk. No:14/1 Arnavutköy, İstanbul, Turkey

**Products:** Conventional Blood Bag Systems, Top and Bottom (K2) Blood Bag Systems, Transfer Bags and Sets, Solutions, Blood Bag Systems with Leukocyte Filter, Platelet Leukocyte Filters (Pooling), Red Blood Cell (RBC) Leukocyte Filter Sets

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

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Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

23 October 2020, Istanbul, Turkey

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