

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

Choose certainty.

Add value.

TO WHOM IT MAY CONCERN

Munich, 2017-07-04

Confirmation concerning certificate QS1 17 03 37258 011

This letter confirms that TÜV SÜD America Inc. issued the ISO 13485:2003 Certificate, No.: QS1 17 03 37258 011, valid until December 31, 2018 to

Fresenius Kabi AG 61346 Bad Homburg Germany

We hereby further clarify and confirm the scope listed in the certificate

includes

 Blood Processing System including device, PC, Software and accessories to these devices

which include the following products

- CompoDock
- CompoMat G5



These products are manufactured by the company

Sanmina-SCI AB Svedjevägen 12 SE-891 23 Örnsköldsvik Sweden

which is certified according to ISO 13485:2003 by TÜV Rheinland (certificate number 74 500 4879, valid until February 28, 2019)

We also confirm that according to European regulatory system, Sanmina-SCI is a third party manufacturer, producing Fresenius Kabi products according to and in compliance with Fresenius Kabi quality and safety specifications and documents.

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH

Medical Health Services

Foreign Affairs