



Product Service

# CERTIFICATE

No. Q1N 16 12 47402 066

**Holder of Certificate:** **Fresenius Kabi AG**

61346 Bad Homburg  
GERMANY

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Sales, Distribution and Service of Active and Non-Active Medical Devices (including Solutions) for Enteral Nutrition, Infusion and Blood Processing

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713092739

**Valid from:** 2017-02-01

**Valid until:** 2020-01-31



**Date,** 2017-01-27

*S. Preiß*  
Stefan Preiß

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**CERTIFICATE**  
**No. Q1N 16 12 47402 066**  
**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems –  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012



Product Service

**Facility(ies):**

- Fresenius Kabi AG**  
61346 Bad Homburg, GERMANY
- Fresenius Kabi Deutschland GmbH**  
**Werk Friedberg**  
Freseniusstrasse 1, 61169 Friedberg, GERMANY
- Fresenius Kabi Deutschland GmbH**  
Gruener Weg 10, 61169 Friedberg, GERMANY
- Fresenius Kabi Deutschland GmbH**  
Production Unit Third Party Manufacturing  
Pfungstweide 53, 61169 Friedberg, GERMANY
- Fresenius Kabi Deutschland GmbH**  
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Robert-Koch-Strasse 5, 36251 Bad Hersfeld, GERMANY
- Fresenius Kabi Deutschland GmbH**  
**Werk Mihla**  
Gartenstrasse 9, 99826 Mihla, GERMANY
- Clinico Medical Sp. z o.o. Blonie k / Wroclawia**  
ul. Roberta Kocha 1  
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- Fresenius Kabi (Nanchang) CO., Ltd.**  
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PEOPLE'S REPUBLIC OF CHINA
- Fresenius Kabi Norge AS**  
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- Fresenius Kabi Italia S.r.l.**  
Via Camagre, 41, 37063 Isola della Scala, ITALY
- Fresenius HemoCare Austria GmbH**  
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- Fresenius HemoCare GmbH**  
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- Fresenius HemoCare Netherlands B.V.**  
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THE NETHERLANDS
- Fresenius Kabi Horatev CZ s.r.o.**  
Hořátev 104, 289 13, CZECH REPUBLIC



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EN ISO 13485:2012 + AC:2012  
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DIN EN ISO 13485:2012

**Facility(ies):**

**Fresenius Kabi España S.A.U.**  
Doctor Ferran 12, 08339 Vilassar de Dalt Barcelona, SPAIN

**Fresenius Vial S.A.S.**  
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**Fresenius HemoCare Brasil Ltda.**  
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