ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 10 63350 061

Holder of Certificate: **Fenwal, Inc.**
Three Corporate Drive
Lake Zurich IL 60047
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Sales, Distribution, Installation and Servicing of active and non-active Medical Devices (including Solutions) for the Collection, Processing and Storage of Blood and Blood Components**

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.: 72109906

Valid from: 2017-07-04
Valid until: 2020-06-30

Date, 2017-07-04

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DAkkS CRT2 / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE
No. Q1N 16 10 63350 061

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

Facility(ies):

Fenwal, Inc.
Three Corporate Drive, Lake Zurich IL 60047, USA

Fenwal International, Inc.
Road 357, Km 0.8, 00606 Maricao, PUERTO RICO USA

Fenwal International, Inc.
Camino Real Industrial Park Road #122, 00683 San German, PUERTO RICO USA

Fenwal France SAS
Etaille, 36-400 La Chatre, FRANCE

Fenwal International, Inc.
Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. de.S.C., Haina, DOMINICAN REPUBLIC

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

Supplement to Quality System Certificate Q1N 16 10 63350 061

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2017-07-04 to

Fenwal, Inc.
Three Corporate Drive
Lake Zurich IL 60047
USA

for the facilities

Fenwal International, Inc.
Camino Real Industrial Park Road #122, 00683 San German
PUERTO RICO USA

Fenwal International, Inc.
Carretera Sanchez Km 18.5, Parque Industrial Itabo
Zona Franca Ind. de S.C., Haina
DOMINICAN REPUBLIC

The quality system certified as stated above additionally fulfills the applicable requirements

1) of **EN ISO 11137-1: 2015 - Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit reports
   - San German / PUERTO RICO: no. 72109903 Dated: 2016-10-13
   - Haina / DOMINCAN REPUBLIC: no. 72101647 Dated: 2015-11-20

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Stefan Preiß
Munich, 2017-07-04

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

Supplement to Quality System Certificate
Q1N 16 10 63350 061

issued by TÜV SÜD Product Service GmbH on 2017-07-04 to

Fenwal, Inc.
Three Corporate Drive
Lake Zurich IL 60047
USA

for the facility

Fenwal France SAS
Etaille, 36-400 La Chatre
FRANCE

The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 17665-1:2006 "Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)"** as documented in the audit report no. 713105488 dated 2017-04-21.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD Product Service GmbH
Certification Body Medical Technology (MHS-CRT)

Munich, 2017-07-04

Stefan Preiß