



CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.

hereby certifies that



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

has implemented a Quality Management System
in accordance with:

ISO 13485:2003

The scope of this Quality Management System includes:

**Design and development, manufacturing, and distribution of
disposables, solutions, systems and accessories for the
collection, processing and storage of blood and blood
components; to include the installation, servicing and
repair of the system medical devices.**

Certificate Expiry Date: October 31, 2011

Certificate Registration No: S 951 03 1645

Original Issue Date: March 13, 2003

Effective Date: November 1, 2008





Gary W. Minks
VP, Regulatory Affairs



Health
Canada
CMDCAS
Recognized
Registrar



CERTIFICATE

Fenwal, Inc.

Three Corporate Drive
Lake Zurich, IL 60047 USA

Scope: Design and development, manufacturing, distribution of disposables, solutions, systems and accessories for the collection, processing and storage of blood and blood components; to include the installation, servicing and repair of the system medical devices.

Fenwal International Inc.

Road 357 km 0.8, 00606 Maricao, Puerto Rico

Scope: Manufacture and distribution of disposables, solutions and accessories for the collection, processing and storage of blood and blood components; to include moist heat sterilization

Fenwal International Inc.

Carretera Sanchez KM 18.5, Parque Industrial Itabo, Zona Franca Ind. de S.C.,
Haina, Dominican Republic

Scope: Manufacture and distribution of disposables and accessories for the collection, processing and storage of blood and blood components. Electron-beam sterilization services

Fenwal International Inc.

Camino Real Industrial Park Road #122
00683 San German, Puerto Rico

Scope: Manufacture and distribution of disposables and accessories for the collection, processing and storage of blood and blood components; to include electron-beam sterilization

Fenwal France SAS

Etaille, 36-400 La Chatre, France

Scope: Manufacture and distribution of disposables, solutions and accessories for the processing, collection and storage of blood and blood components; to include electron-beam and moist heat sterilization.

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