



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. **G2S 15 02 74735 025**

Manufacturer:**Covidien llc**

15 Hampshire Street
Mansfield MA 02048
USA

EC-Representative:**Covidien Ireland Limited**

IDA Business and Technology Park
Tullamore
IRELAND

**Product
Category(ies):**

**Medical Devices for Wound Care and
Closure,
Cardio-Thoracic-Respiratory, Blood
Collection,
Suction/Aspiration/Gastro-Intestinal
Management, Urology,
Enteral Feeding, Operating Room Support
Products
and Needles and Syringes for Aspiration or
Irrigation
as specified in the attachment to this
certificate**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

00702100170

Valid from:

2015-05-22

Valid until:

2020-02-23

Hans-Heiner Junker

Date, 2015-05-27

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 15 02 74735 025

Facility(ies):

Covidien llc
15 Hampshire Street, Mansfield MA 02048, USA

Covidien
2010 E. International Speedway Blvd., Deland FL 32724, USA

Covidien
1222 Sherwood Road, Norfolk NE 68701, USA

Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C.,
MEXICO

Covidien Ireland Limited
Tullamore Business and Technology Park, Srah, Tullamore, Co.
Offaly, IRELAND

Covidien
1430 Marvin Griffin Road, Augusta GA 30906, USA

Covidien (Kenmex Medical Specialties)
Calle 9 Sur 1113, Ciudad Industrial, 22444 Tijuana, Baja
California, MEXICO

Covidien llc
117 Moo 2, Petchkasem Road, Sampran, Nakorn-Pathom 73110,
THAILAND



Attachment for Certificate G2S 15 02 74735 025
Dated 2015-05-27

Facilities and Products included:

Covidien (Manufacturing Only) (Client 69635)
 2010 E. International Speedway Blvd., Deland, FL 32724 USA

Needles and Syringes for aspiration or irrigation

- Irrigation and Oral Feeding Syringes

Covidien (Manufacturing Only) (Client 69637)
 1222 Sherwood Road, Norfolk, NE 68701 USA

Needles and Syringes for aspiration or irrigation

- Irrigation and Oral Feeding Syringes
- Tuberculin Syringes

Covidien (Manufacturing Only) (Client 74165)
 Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C., MEXICO

Blood Collection Devices

- Blood Collection Sets

Respiratory Devices

- Mucus / Specimen Collectors

Operating Room Support Products

- Tip Polisher

Covidien llc (Manufacturing Only) (Client 74733)
 117 Moo 2, Petchkasem Road, Klongmai Sampran, Nakorn-Pathom 73110, THAILAND

Urological Drainage Devices

- Urine Collection Bags

Wound Care Devices

- Eye Patch

Covidien Ireland Limited (Manufacturing Only) (Client 64527)
 Srah, Tullamore Business & Technology Park, Co. Offaly Tullamore, Ireland

Cardio-Thoracic-Respiratory Devices

- Drainage Systems and Tubing Sets

Enteral Feeding Devices

- Gravity Feeding Sets

Suction /Aspiration / Gastro-intestinal Management Devices

- Connecting Tubes and Adapter

Urology Devices

- Urine Collection Devices
- Urinary Leg Bags and Drain Bags



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- Vaginal Irrigation Sets

Covidien (Manufacturing Only) (Client 69724)
1430 Marvin Griffin Road, Augusta GA 30906, USA

Wound Care and Closure Devices

- Woven and Non-woven Primary and Secondary Wound Dressings
- Padding
- Sponges
- Skin Wipes With Alcohol Solution

Covidien (KenMex Medical Specialities) (Manufacturing Only) (Client 70797)
Calle 9 Sur 1113 Ciudad Industrial, 22444 Tijuana, Baja California, MEXICO

Needles and Syringes for Aspiration or irrigation

- Syringes and tip caps

Urology Devices

- Urine Collection Devices
- Urinary Bags
- Urine Leg Bags and Drain Bags

Suction /Aspiration / Gastro-intestinal Management Devices

- Connecting Tubes and Tubing Connectors
- Feeding Sets
- Tube Access
- Suction Tubing

Operating Room Support Products

- Light Handle Systems
- Surgical Drapers / Markers
- Transfer Trays
- Blade Shield
- Tube Holders
- Devon Pouch
- Clamp Drapers / Magnetic Drapers

Munich, CRT2, 2015-05-27

Hans-Heiner Junker