Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

Manufacturer: **Covidien LLC**
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): **Circular Staplers,**
Linear Staplers and Cartridges

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1958501

Valid from: 2020-01-17
Valid until: 2024-05-26

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

Facility(ies):

Covidien LLC
15 Hampshire Street, Mansfield MA 02048, USA

Covidien (China) Medical Devices Technology Co., Ltd.
Rooms 501, 502, 601, 602, No.3 Building, No.2388, Chen Hang Road, Min Hang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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

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

TÜV®

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

For the product(s)/product category (ies):

Covidien llc
15 Hampshire Street, Mansfield MA 02048, USA

Legal manufacturer

Covidien (China) Medical Devices Technology Co., Ltd.
Rooms 501, 502, 601, 602, No.3 Building, No.2388, Chen Hang Road, Min Hang District, 201114 Shanghai, People's Republic of China

Circular Staplers, Linear Staplers and Cartridges

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Circular Staplers

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Linear Staplers and Cartridges

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

Manufacturer: **Covidien LLC**
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): **Circular Staplers,**
Linear Staplers and Cartridges

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1958501

Valid from: 2020-01-17
Valid until: 2024-05-26

Date, 2020-01-17

Christoph Dicks
Head of Certification/Notified Body

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

Facility(ies):

Covidien LLC
15 Hampshire Street, Mansfield MA 02048, USA

Covidien (China) Medical Devices Technology Co., Ltd.
Rooms 501, 502, 601, 602, No.3 Building, No.2388, Chen Hang Road, Min Hang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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

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

TÜV®

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 088795 0029 Rev. 00

For the product(s)/product category (ies):

Covidien llc
15 Hampshire Street, Mansfield MA 02048, USA

Legal manufacturer

Covidien (China) Medical Devices Technology Co., Ltd.
Rooms 501, 502, 601, 602, No.3 Building, No.2388, Chen Hang Road, Min Hang District, 201114 Shanghai, People's Republic of China

Circular Staplers, Linear Staplers and Cartridges

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731, USA

Circular Staplers

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Linear Staplers and Cartridges

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