

The management system of

Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 06866

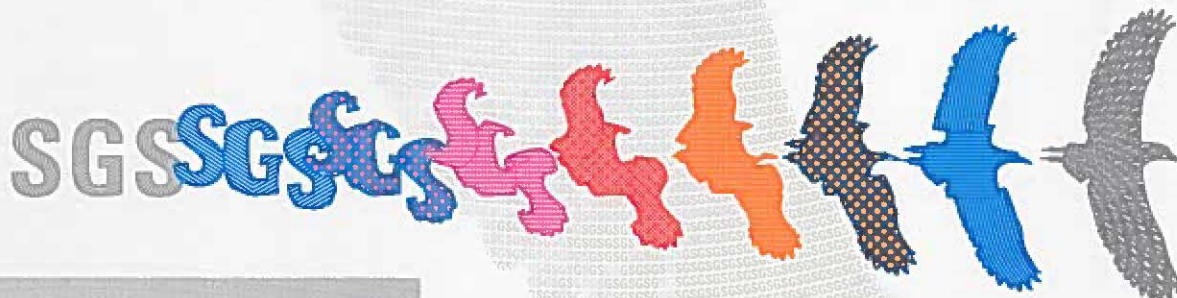
Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev 02

Page 1 of 3



Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

- Sterile Hem-o-lok and Vesolock Ligation Clips,**
- Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesoclude**
- Metal Ligation Clips Sterile Deknatel® PTFE pledgets.**
- Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II,**
- "silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®).**
- Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM**
- and polypropylene non-absorbable surgical sutures.**
- Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical**
- Sutures. Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.**
- Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.**
- Sterile Hem-o-lok Automatic Clip Appliers.**
- Metal Ligation System.**

- Sterile and Non-sterile External stapling system (including stainless steel staples,**
- staplers and removers), Sterile, Efx endo fascial closure system (abdominal access),**
- Sterile, Efx shield fascial closure system (abdominal access),**
- Sterile, Efx classic fascial closure system (abdominal access)**
- Sterile stainless steel surgical Sutures**
- Sterile FORCE FIBER® surgical sutures.**
- Sterile Chest drainage and autotransfusion systems, Sterile Thoracic Catheters,**
- Sterile and Non-sterile Aortic Punch,**
- Non-sterile Self Retaining Tissue retractor/blades**



Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

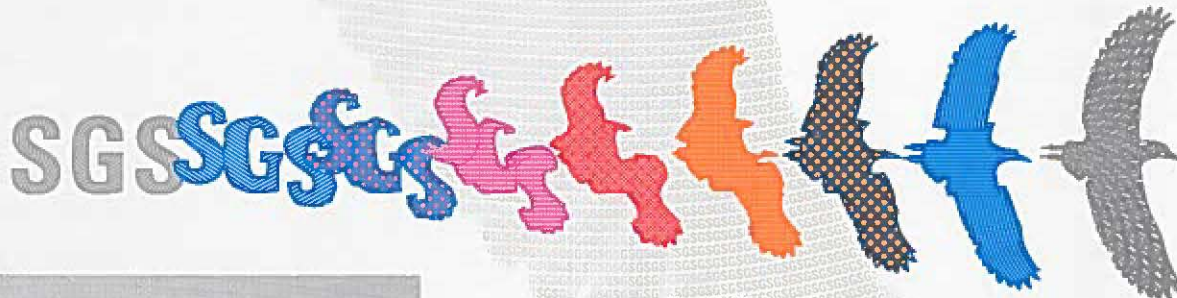
Detailed scope

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non-sterile Respiratory and anaesthesia masks, Non-sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States



EC Certificate Production Quality Assurance System: Certificate US19/819943646.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 01 February 2020 until 14 July 2023 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 26 September 2000 and first certified by SGS Belgium NV since 01 February 2020

Certification is based on reports numbered WW/MC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US19/819943646.00

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

Page 1 of 2



Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions

Issue 1

Detailed scope

**Sterile Suture Guides, Sterile Belly Bags (Urine Collection Device),
Sterile stapler removers.**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States



Certificate US97/10878.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 15 July 2021 until 14 July 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 22. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00
This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

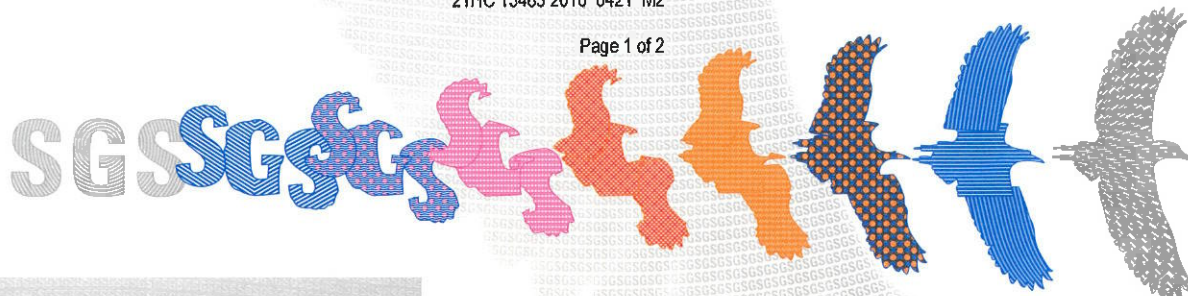


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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421 M2

Page 1 of 2



Teleflex Medical

ISO 13485:2016

EN ISO 13485:2016



Issue 22

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices.

Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material..

Manufacturing of sterile single use absorbable and non-absorbable sutures.

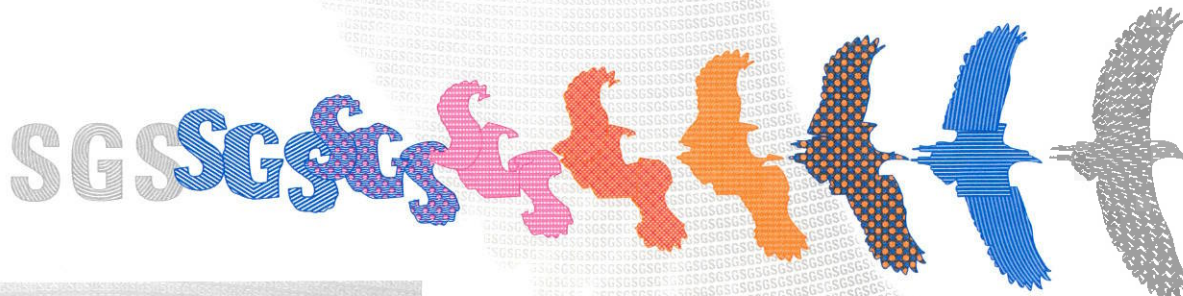
Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States



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EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

**Endoscopic instruments, HF-instruments and accessories,
Needle systems and Drainage systems
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

| | |
|------------------|------------------|
| Valid from | 2021-04-15 |
| Valid until | 2024-05-26 |
| Registration no. | D1033500044 |
| Report no. | P20-01643-203710 |
| Stuttgart | 2021-04-15 |



Head of Certification Body



Attachment of the certificate

No. D1033500044

Date 2021-04-15

Page 1 of 1

| Product category | Product | Class |
|--------------------------------|---|-------|
| Drainage systems | Nasal Biliary Drainage Probes SU | Ila |
| | Biliary Stents SU | IIb |
| | Pancreatic Stents SU | IIb |
| | Self-expanding Stents SU (Biliary, Bronchial/Tracheal, Colonic, Duodenal, Esophageal) | IIb |
| Endoscopic instruments | Stone extraction Balloons SU | Ila |
| | Biopsy Forceps SU/RU | Ila |
| | Foreign Body Retrievers / Polyp Retrievers SU/RU | Ila |
| | Multi Band Ligation Device SU | Ila |
| | Spray Catheters SU | Ila |
| | Cytology Brushes SU | Ila |
| | Guide Wires SU | Ila |
| HF-instruments and accessories | Cysto Gastro Sets SU | IIb |
| | HOT Biopsy Forceps SU | IIb |
| | Sphincterotomes SU/RU | IIb |
| | Polypectomy Snares, Mukosectomy Snares SU/RU | IIb |
| Needle systems | Fibrin Application Needles SU | Ila |
| | FNA Systems for ultrasound endoscopy SU | Ila |
| | Injection Needles SU | Ila |
| | Transbronchial Aspiration Needles SU | Ila |



Head of Certification Body



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

Endoscopic instruments
(see attachment)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and
maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system
meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

| | |
|------------------|------------------|
| Valid from | 2021-05-14 |
| Valid until | 2024-05-26 |
| Registration no. | D1033500045 |
| Report no. | P20-01767-205939 |
| Stuttgart | 2021-05-14 |



Head of Certification Body



Attachment of the certificate

No. D1033500045

Date 2021-05-14

Page 1 of 1

| Product category | Product | Class |
|------------------------|---|------------|
| endoscopic instruments | E.R.C.P. Catheters SU Suction / Flushing Catheters SU Stone Extraction Baskets SU/RU Lithotripsy Baskets / Lithotripsy Spirals SU/RU Guiding Catheters SU Pushers SU Stent Placement Sets SU Biliary Dilation Catheters SU Polyp & Foreign Body Retriever "EasyCollect" SU Guide Wires SU/RU Dilation Balloons SU | I (steril) |



A handwritten signature in blue ink, appearing to read "AGC", is written above a horizontal line.

Head of Certification Body

Certificate

mdc medical device certification GmbH
certifies that



ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

with the locations listed in the attachment
for the scope

**design, development, production, storage and distribution of
instruments and accessories for the diagnostic and therapeutic endoscopy**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

| | |
|------------------|------------------|
| Valid from | 2021-05-14 |
| Valid until | 2023-02-03 |
| Registration no. | D1033500046 |
| Report no. | P20-01767-189354 |
| Stuttgart | 2021-05-14 |

A handwritten signature in blue ink, appearing to read "NHC".

Head of Certification Body



Attachment of the certificate

No. D1033500046

date 2021-05-14

Page 1 of 1

| Location | Scope |
|--|---|
| ENDO-FLEX GmbH Alte Hünxer Straße 115 46562 Voerde | design, development, production, storage and distribution of instruments and accessories for the diagnostic and therapeutic endoscopy |
| ENDO-FLEX GmbH Südring 21 46342 Velen-Ramsdorf | storage and distribution of instruments and accessories for the diagnostic and therapeutic endoscopy |





Head of Certification Body

EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany**

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system
**for the aspects of manufacture concerned with securing and maintaining
sterile conditions**

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12

Expiry date: 2024-05-27

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB415200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB415200310

List of locations included in the scope of certificate

**Meessen 9
22113 Oststeinbek
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB415200310

List of products / product categories included in the scope of certificate**Medical devices for Urology**

- **Catheters**
- **Catheter accessories**
- **Urine-drainage systems**

– End of list –

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MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



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ZLG-BS-237.10.15

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12
Expiry date: 2024-05-27

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB410200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB410200310

List of locations included in the scope of certificate

**Meessen 9
22113 Oststeinbek
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB410200310

List of products / product categories included in the scope of certificate**Medical devices for Urology**

- **Biopsy guns**
- **Catheters**
- **Catheter sets**
- **Guide wires**
- **Stone retrieval baskets**
- **Cannulas**
- **Dilators**
- **Ureteral stents**

– End of list –

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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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www.zlg.de
ZLG-BS-237.10.15

Certificate

The certification body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany**

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

**Design and development, manufacture, final inspection and distribution of
medical devices for**

- **Urology**
- **Gynecology**
- **Radiology**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12

Expiry date: 2023-03-12

Report No.: 1202FS27F
Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems
certification body



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

Appendix of certificate

Procedure No.: QS – 1202

Certificate No.: 1202GB445200310

List of locations included in the scope of certificate

**Meessen 9
22113 Oststeinbek
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT is a DAkkS accredited management systems
certification body



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00