CERTIFICATE

for the
Quality Assurance System

DEKRA Certification

As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for manufacture and final inspection by the company

Willy Rüsch GmbH

Willy-Rüsch-Str. 4-10 • 71394 Kernen, Germany

Approval is based on the decision dated 22.10.2010 and the result of the report no. 50017-Z4-00 and is performed in accordance with the stipulations of

Annex V, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex V, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	25.10.1995	Date of the last recertification:	24.10.2010
This certificate is valid until:	23.10.2015	Certificate-registration No.:	50017-17-03

English version

DEKRA Certification GmbH
Stuttgart, 22.10.2010

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the Certificate 50017-17-03 dated 22.10.2010

English version

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Devices/device categories included in the certificate

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

Respiratory device

- Tracheal tube
- Oropharyngeal Tube
- Suction Catheter
- Bronchial Catheter

Surgical devices

- Drainage tube

Urology device

- Urine collection Bag
- Perineal Drape
- Urethral Catheter
- percutaneous Nephrostomy Catheter
- Ureter Catheter
- Urodynamic Catheter
- Suprapubic cannula
- Urethral/Suprapubic catheter

Digestive tract device

- Rectal Tube

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the manufacturing steps associated with product conformity and metrological requirements.

Respiratory device

Manometer