

Certificate

The Certification Body

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

herewith confirms that the company

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany

With its facilities as per attachment 1

has introduced, applies and maintains a Quality Management System in the area of:

Design, manufacture, final inspection and distribution of
Medical Devices as per attachment 2 to 3

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2012 + AC:2012

This certificate is valid until: 31 March 2019

Report No.: 0521PS29F
Process No.: QS - 0521
Certificate No.: 0521GB438171204

Hamburg, 04 December 2017



MEDCERT Certification Body
(Dr. Andreas Schich)



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

**Attachment 1
Certificate
QS – 0521**

This attachment is valid only in connection with certificate No: 0521GB438171204

Facilities

**Primed Halberstadt Medizintechnik GmbH
Am Bahndamm 11
38820 Halberstadt
Germany**

**Primed Halberstadt Medizintechnik GmbH
Am Domplatz 34
38820 Halberstadt
Germany**

Hamburg, 04 December 2017



MEDCERT Certification Body
(Dr. Andreas Schich)

Attachment 2
Certificate
QS – 0521

This attachment is valid only in connection with certificate No: 0521GB438171204

- **Anuscope**
- **Sets for autologous transfusion**
- **Bacterial and viral filters**
- **Dosage systems for bladder-instillation**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Colon-preparation systems**
- **Disinfectants**
- **Dilatation-sets for percutaneous tracheostomy**
- **3-way stopcocks**
- **Duodenal tubes**
- **Feeding tube, tubes of small intestine and suction tubes**
- **Loops**
- **Infusion and drainage accessories**
- **Intra uterine pessaries (IUP)**
- **Tracheal cannula necklaces**
- **Catheter valves**
- **Articles for general hospital supplies**
- **Artificial noses (HME) with and without O2-connector and their accessories**
- **Laser catheters and their accessories for laser application**
- **Stomach tubes**

Hamburg, 04 December 2017



MEDCERT Certification Body
(Dr. Andreas Schich)

Attachment 3
Certificate
QS – 0521

This attachment is valid only in connection with certificate No: 0521GB438171204

- **Mixing and urine bags**
- **Gingivodental orthopaedic devices**
- **Nasal splints and tamponades**
- **Ventilation tubes**
- **Pessaries**
- **Redon-systems**
- **Oxygene cannulas**
- **Suction tubes and suction connecting tubes**
- **Speaking valves with respiration connection**
- **Fecal management system**
- **Overdentures**
- **Thoracic and trocar catheters**
- **Tracheostomy cannulas, stents and applicators**
- **Transfusion devices for blood bags**
- **Transmission systems**
- **Urine beakers**
- **Urine drainage and pump tubing systems and their accessories**
- **Urine measuring drainages**
- **Wound foams**
- **Compilation of blood collection sets**

Hamburg, 04 December 2017



MEDCERT Certification Body
(Dr. Andreas Schich)