

EC-Certificate of Conformity

The Notified 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

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:

Medical devices as per attachment 1

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid from 01 April 2016 until 31 March 2021

Report No.: 0521FS28F
Process No.: QS -0521
Certificate No.: 0521GB415160331

Hamburg, 31 March 2016

MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482



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

Attachment 1 EC-Certificate of Conformity QS - 0521

This attachment is valid only in connection with certificate No: 0521GB415160331

- **Anusscopes**
- **Dosage systems for bladder-instillation**
- **Duodenal tubes**
- **Infusion and drainage accessories**
- **Catheter valves**
- **Stomach tubes**
- **Mixing bags**
- **Nasal tamponades**
- **Stomach tubes, Suction tubes and suction connecting tubes**
- **Transmission systems**
- **Urine bags**
- **Urine beakers**
- **Accessories for tracheal cannulas**

Hamburg, 31 March 2016


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