

# 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:

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

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

**Effective date: 2020-04-24**

**Expiry date: 2024-04-01**

Report No.: 0521PS33F

Process No.: QS – 0521

Certificate No.: 0521GB410200424

Hamburg, 2020-04-24

  
MEDCERT Certification Body  
(Lorenz Runge)

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

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

**Appendix of EC Certificate of Conformity**

Process No.: QS – 0521

Certificate No.: 0521GB410200424

**List of locations included in the scope of certificate****Am Bahndamm 11  
38820 Halberstadt  
Germany****Domplatz 34  
38820 Halberstadt  
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Certificate of Conformity

Process No.: QS – 0521

Certificate No.: 0521GB410200424

### List of products / product categories included in the scope of certificate

- **Sets for autologous transfusion**
- **Bacterial-and viral filters**
- **Brachytherapy catheters**
- **Brachytherapy needles with goldmarker**
- **Disinfectants**
- **Loops**
- **Intra uterine pessaries (IUP)**
- **Artificial noses (HME) with O2-connector and their accessories**
- **Dilation sets for percutaneous tracheostomy**
- **Pump tubing systems and their accessories**
- **Redon-systems**
- **Oxygene cannulas**
- **Speaking valves with respiration connection**
- **Suction catheters**
- **Fecal management systems**
- **Thoracic and trocar catheters**
- **Tracheostomy cannulas, stents and -applicators**
- **Transfusion devices for blood bags**
- **Wound Foams**

– End of list –

This appendix is integral part of the above-referenced certificate.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15