

**TÜV Rheinland**  
**Product Safety GmbH**  
**Am Grauen Stein, D-51105 Köln**

Doc. 1/1, Rev. 0


**Attachment to**  
**Registration No.:** CT 4300305 0012  
**Report No.:** 34001315 002

**Manufacturer:** Ecomed (HongKong)  
Industry Co., Limited.  
B10, 5/F, Huafeng Times  
Square Building,  
  
Bao'an District, Shenzhen  
China

**Scpoe:** Production facility:  
  
Ecomed (Hongkong) Industry Co., Limited.  
B10, 5/F, Huafeng Times Square Building,  
25 Subdistrict, Bao'an District,  
Shenzhen 518101, China

**Cologne,** 10.02.2016

**Certification Body**



TÜVRheinland  
Zertifizierungsstelle

**Dipl.-Ing. D. Meier**

**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

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Bao'an District, Shenzhen  
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**Scope:** Design/Development and Manufacturing of Ultrasound  
Diagnostic Scanners, Patient Monitors, Infusion Pumps,  
X-Ray Accessories (X-Ray Film Processors and X-Ray Film  
Viewers)  
Production facilities: see attachment  
Replaces Approval, Registration No.: BF 7113364 0011

**Date of Expiry:** 09.04.2018

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 10.02.2016

Notified Body  
  
Dipl.-Ing. D. Meier

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE