

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

Registration No.: HD 60024991 0001

Report No.: 26300051 002

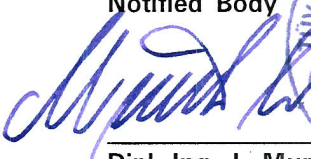

**Manufacturer:** BRAEL - Aparaty Medyczne  
Pawel Brancewicz  
ul. Moscickiego 1  
24-110 Pulawy  
Poland

**Scope:** Design/development and production of active medical devices  
(see attachment for products included)

**Date of Expiry:** 10.03.2014

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, 15.05.2009

Notified Body  
  
Dipl.-Ing. I. Munkler  


**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

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

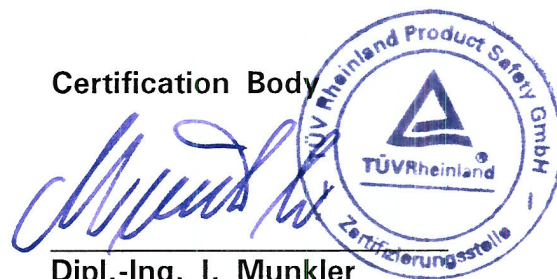
**Attachment to**  
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**Manufacturer:** BRAEL - Aparaty Medyczne  
Pawel Brancewicz  
ul. Moscickiego 1  
24-110 Pulawy  
Poland

**Scope:** Products:  
  
- Doppler fetal heart detectors  
- Fetal monitors

Cologne, 15.05.2009

Certification Body



Dipl.-Ing. I. Munkler