

# Declaration of Conformity

pursuant to the Act No. 22/1997 Coll., Sec. 13, Art. 2 and the government Decree No. 336/2004 Coll., Sec. 9

**Manufacturer:** AMV technics s.r.o.  
Wáagnerova 1715  
666 01 Tišnov  
Company ID: 25532600  
Entered in the Commercial Register kept by the Regional Court in Brno,  
insertion 31067

**Product Identification Data:**  
Syringe pump TECHNIC I

**Product Description:**  
Syringe pump designed for accurate application of low-volume infusions using disposable syringes of 10, 20, 30 or 50 ml volume

**Conformity Assessment Method:**  
The product sample was analysed in accordance with the government Decree No. 336/2004 Coll., Section 9, Article 3(IIb class), Annex No. 2 and 3.

**List of Technical Regulations and Harmonized Technical Standards Used in Assessing the Conformity:**

- ČSN EN 60601-1-1 Requirements for safety of medical systems
- ČSN EN 60601-1-2 Electromagnetic compatibility
- ČSN EN 60601-1-4 General requirements for programmable electrical medical systems
- ČSN EN 60601-2-24 Particular requirements for safety of infusion pumps and controllers

**Authorized Person Involved in Assessing the Conformity:**

- Strojírenský zkušební ústav, s.p., notified body of the European Community 1015, authorized body 202, Hudcova 56b, 621 00 Brno, Company ID: 00001490
- VOP-026 Šternberk s.p., divize VTÚPV Vyškov, V. Nejedlého 691, 682 03 Vyškov

**Certificates:**

- EC type examination certificate No. E-30-01012-09  
This product was subjected to the EC type examination in accordance with Annex III to the Council Directive 93/42/EEC (Annex No. 3 to the government Decree No. 336/2004 Coll.).
- EC certificate No. E-40-00749-09  
This medical device was subjected to the assessment of full quality assurance system in accordance with Annex II to the Council Directive 93/42/EEC (Annex No. 2 to the government Decree No. 336/2004 Coll.).

**Manufacturer's confirmation:**

AMV technics s.r.o. as the manufacturer confirms the product properties meet the basic requirements set by the government Decree No. 336/2004 Coll. and the technical standards above.

In Brno on September 31, 2009

Alexandr Mihál  
Recognized Agent

  
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