

# EC Declaration of Conformity



Document No. 604.005

Product: **BIOSEN C-Line**  
**“Clinic”, “Sport”, “GP” and “GP+”**  
**with auxiliary equipment and consumables**

We herewith declare that the above mentioned product meets the provisions of the Council Directive

**98/79/EC** **In Vitro Diagnostic Medical Devices**

**89/336/EEC** **Electromagnetic Compatibility**  
last alteration: 93/68/EEC

**73/23/EEC** **Low Voltage Directive**  
last alteration: 93/68/EEC

which is proven by meeting completely the following standards:

**EN 61010-1**  
**EN 61010-2-101**  
**EN 61326**  
**EN 13612**

**EN 60601-1-2**  
**EN 55011 class B**  
**EN 61000-3-2/-3-3**  
**EN 13640**

**EN ISO 14971**  
**EN 1658**  
**EN 591**  
**EN ISO 17511**

This declaration certifies the conformity with the mentioned requirements but an assurance of quality is not included.  
The safety notes of the delivered product documentation are to be followed.

Manufacturer: **EKF-diagnostic GmbH**  
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Issuer, function: **B. Walter (General Manager)**

Barleben, 16. 02. 2004  
Place, Date of issue

.....  
legally binding signature

#### Anschrift

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#### Geschäftsführer

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#### Bankverbindungen

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