

/letterhead/

**Przedsiębiorstwo BENE sp. j.**

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**TÜV**

**CERT**

ISO 9001:2000

ZN: 75.100.30184

**BENE**

**TÜV Rheinland InterCert**

**DECLARATION OF CONFORMITY**

according to Annex VII to Council Directive 93/42/EEC

We:

Przedsiębiorstwo BENE Sp. J.

B. Mieżyński, A. Mieżyński, M. Taranda, P. Wielopolski

71-220 Szczecin, ul. Modra 66/68

declare under our sole responsibility that our products:

- **sterile single use vaginal specula small size**
- **sterile single use vaginal specula medium size**

are certified with the participation of Notified Body No. 1434 and comply with the general requirements set out in Annex I to Directive 93/42/EEC, as well as the Law on Medical Products dated 20<sup>th</sup> April 2004 and the Ordinance of Minister of Health dated 3<sup>rd</sup> November 2004 on Essential Requirements for Multipurpose Medical Products.

**According to Annex IX to Directive 93/42/EEC and the Ordinance of Minister of Health dated 30<sup>th</sup> April 2004 on Classification of Multipurpose Medical Products, we classify them as:**

**Class I medical products - sterile.**

On the basis of this Declaration of Conformity we affix **the CE marking** to the products.

Signature stamp: "BENE" Registered Partnership  
P R E S I D E N T  
/illegible signature/  
Bogdan Mieżyński

Szczecin, 23<sup>rd</sup> October 2006.

This is to certify the conformity of the translation with the presented document  
in the Polish language.  
Szczecin, 2006-10-28.



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