

/letterhead/

**Przedsiębiorstwo BENE sp. j.**

Bogdan Mieżyński, Andrzej Mieżyński, Maciej Taranda, Paweł Welopolski  
ul. Modra 66-68, 71-220 Szczecin  
tel +4891 43 94 552, +4891 43 94 469, fax +4891 43 94 461

**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 that our product:

**sterile single use gynobrush 20 cm**

is certified with the participation of Notified Body No. 1434 and complies 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 it as:**

**Class I medical product - sterile.**

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

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

Szczecin, 4<sup>th</sup> September 2006.

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



COURT SWORN  
TRANSLATOR AND INTERPRETER  
ENGLISH  
Aleksander Swatex, MSc  
tel.: (091) 48-707-23, 0-50  
e-mail: alswat@pocz  
ul. Reymonta 61, 71-276