

/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 laryngological spatula PS**

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 20th April 2004 and the Ordinance of Minister of Health dated 3rd 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 30th 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, 4th 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 Swiatko, MSc in E.I.E.
tel.: (091) 48-707-23, 0-501-508-975
e-mail: alswat@poczta.fm
ul. Reymonta 61, 71-276 Szczecin