

**DIRECCION GENERAL DE
FARMACIA Y PRODUCTOS
SANITARIOS
ORGANISMO NOTIFICADO N° 0318
DGFPS: P° del Prado 18-20. 28014 Madrid (España)
Tfno. (91) 5964643 Fax (91) 5964400**

CE DECLARATION OF CONFORMITY

Directive 93/42/CEE ABOUT SANITARY PRODUCTS - ANNEX VII -

REF. : OPERFILM (ADHESIVE MEMBRANE, FAMILY 31)

Mr. Aniceto López Rodríguez

Addressed in Pau Casals num. 13 of Parets del Vallés (Barcelona - SPAIN)

In name and in representation of the company IBERHOSPITEX S.A.

Addressed in Avda. de Catalunya num.4 , 08185 Lliça de Vall (BARCELONA - SPAIN)

Declares:

That the sanitary product described in the following pages accomplishes the essential requirements established in the Annex I of the Directive to which it belongs, and therefore any compromise for health and the security of the people is guaranteed, always if the product is used according to its previewed final use, as well as offering the established proprieties.

Undertakes:

To establish and maintain updated the systematic process of reviewing the acquired experience with the products in the further phases of production, using all the required methods to apply the necessary corrections.

Undertakes:

To inform to the competent authorities about the following facts as soon as he knows them:

a) Any defective or alteration in the characteristics or proprieties, as well as any not suitable in the labelling or in the instruction of use of the product which may originate death or high alteration of the health of the patient or user.

b) Any technical or sanitary reason, related with its characteristics or with the proprieties of any product mentioned in the previous paragraph, which has obliged to the manufacturer to withdraw systematically of the market the products which belong to the same range of product.

IBERHOSPITEX S.A.

IBERHOSPITEX, S.A.

A. López Rodríguez

Date: 22nd of April 1998