

To whom it may concern

Declaration of Innocuousness

The medical product **Ultrasound Gel**, a product as per Class 1 of Directive 93/42/EEC, produced by Primax Berlin GmbH in 12681 Berlin Meeraner Strasse 17e, can be treated as widely harmless because of the exclusive utilisation of basic substances which have been used in the pharmaceutical and cosmetics production for years.

By means of the production method and the quality assurance system it is guaranteed that no additional risk resulting from any external hazard to the product will occur during application.

Any malpractice or misuse is virtually excluded because of the kind of application (by doctors or registered nurses).

Berlin, 3rd July, 2008

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