

## MARKET SURVEY ON NATURAL RUBBER LATEX MEDICAL GLOVES

Considering the allergy risk related to natural rubber latex, the DEDIM carried out a market survey on the latex medical gloves. Objectives of this survey are as follows:

- Checking the implementation by manufacturers of glove manufacturing processes allowing the reduction of allergy risks in relation to latex proteins to the feasible lowest levels
- Checking the information intended for users related to the residual risk

The Survey focused on 38 exam and surgery gloves usually used in french hospitals : assays of leachable proteins and checks of labellings and users technical documents provided by the manufacturer are the two steps of this survey.

Results confirm the homogeneity of the market regarding amounts of leachable proteins. Manufacturers claims are in compliance with the results found at the time of of the survey, i.e. lower than the mean amount 100µg/g.

Concerning labellings and users technical documents, the information provided was generally satisfying. Few nonconformities were detected mainly on examination gloves (class I medical devices) and primarily due to misinterpretation of the essential requirements of the medical device Directive 93/42/CEE. These deviations were quickly corrected after having informed of the manufacturers involved.

Therefore, in order to reach a common interpretation of the medical device Directive provisions with regard to the risk of natural rubber latex, guidelines will be published soon by the European Commission following a workshop that Afssaps attended.