INTRODUCTION
A few mass outbreaks of irritant contact dermatitis (ICD) among medical stuff used medical gloves initiated its risk assessment. Irritant contact dermatitis is caused by residues of hazardous processing chemicals on gloves surface coupled with the irritation caused by frequent hand washing, strong surgical scrub agents, soaps and detergents. Because of continued every day gloves use, chemicals damage the surface of the skin faster than the skin is able to repair the damage (Fig.1). Bioavailability of complicated cocktail of chemicals can be evaluated by cytotoxicity testing. It is known that cytotoxicity and irritation test results are correlating closely. Different brands of latex, isoprene and nitrile medical gloves have been tested for cytotoxicity to assess the risk of ICD.

METHODS AND MATERIALS
Cytotoxicity was evaluated in accordance with ISO 10993.5. Prime culture of bull spermatozoa was used. Frozen cells were stored in liquid nitrogen. Weighted average time of spermatozoa suspension motility was used as the test-parameter. The motility of spermatozoa suspension in control and test samples were measured by Cytotoxicity Analyzer AT-05. This technology permits to evaluate cytotoxicity in 3 hours and to investigate not steril extracts. The operator can control in real time the cytotoxicity evaluation process visually on monitor (Fig.2). If extract is highly cytotoxic result becomes evident in a few minutes. The distilled water of 250 ml is poured into the inside surface of the glove. The extraction is performed under the conditions prescribed by ISO 10993-12: 37 ºC within 24 hours. The gloves surface chemicals are thermo-stable and easy-extractable. Extraction within 15 minutes at 100 ºC can be used for risk assessment to reduce time of whole assessment to 4 hours.

RESULTS
62 brands were tested. To estimate level of risk, cytotoxicity of different extract dilutions (dilution step of 2) was evaluated (Fig.3). 7 brands appeared not cytotoxic. Others were cytotoxic in different dilutions from 1:2 up to 1:128. It means that these extracts comprise chemicals of clinical importance of high concentration. About 75% of tested gloves were cytotoxic in dilutions higher than 1:16. The test result does not depend either on the surface of the glove – inside or outside – to be tested or on the purpose of the glove – exam or surgical. For different lots of the same brand result may fluctuate within a few dilution steps. The results above are practically the same for gloves made from natural rubber latex and gloves made from currently available synthetic alternatives. Gloves which gave rise to mass ICD were cytotoxic in dilution higher than 1:32.

CONCLUSIONS
• We must state that most of medical gloves available on the market contain on their surface chemicals which provoke ICD. The product has no labels warning customers about ICD risk.
• Cytotoxicity testing with prime culture of bull spermatozoa permits to estimate ICD risk level adequately, quickly and with minimum cost.
• Up-to-date state of the art do not permit to produce medical gloves free from hazardous chemicals. To improve situation we propose:
  - product labelling needs to include a warning that the product may contribute to ICD;
  - ICD risk level limit – minimum not cytotoxic extract dilution must be established;
  - manufacturer must perfect the gloves leaching process to reduce residual quantities of chemicals.

Fig. 1 Irritant contact dermatitis.

Fig. 2 Cytotoxicity experiment information is shown on monitor in real time.

Fig. 3 Effect on bull spermatozoa suspension motility. Different glove extract dilutions.