[redacted]

86

ETHYLENE OXIDE RESIDUALS

Poly Implant Prostheses (PIP) sterilizes its silicone gel range of implants, subject of this application, by exposing to ethylene oxide gas. It is essential that the manufacturer have in place a procedure to ensure that residual gas is within the acceptable tolerance limit specified by standards or by alternative procedures validated for that purpose.

PIP ref: MXM/00-0019 incorporates Document: CHGPIP, Distribution:3, addresses the methodology and testing program utilized by the company to assess the ethylene oxide residues subsequent to sterilization.

Each load of product undergoing sterilization includes two samples, representative of the load that are characterized by a prolonged desorption time, are placed strategically in the load. Only one sample is tested, the second sample is stored in case of a non-conforming first result.

The procedure, CHGPIP, used by the testing laboratory, MXM, is based on the European Pharmacopoeial method. The sample extracted with water includes both shell and silicone gel materials of the implant, and the extractant is analysed for residuals by gas chromatography.

The release criterion is ≤0.5 ppm.

This is acceptable and well within prescribed limits of ISO 10993 – 7 *Ethylene Oxide Sterilization Residuals*

[redacted]

[redacted]

87

RISK ANALYSIS
Submission No. 2003/098

PIP adopted the procedures of NF EN 1441 to perform Risk Analysis of the manufacture of the High Cohesivity Silicone Gel Breast Implants and report in document Reference SQ1/02 DOT 202.

The company has taken each element of the standard and examined the parameter for potential hazards. Identified risks and hazards are correlated with solutions or monitoring mechanisms together with the series of documents in the company's system established to address each of the identified potential risks or hazards. All the documents in the system are listed, titled and discussed within the supporting data.

One "hazard" has not been identified under the clause "Influences on the environment" or a solution presented which will be of increasing importance – disposal of explanted silicone elastomer and gel material. As this does not relate specifically to the safety or performance of the medical device, the matter will not be followed for establishing conformity assessment.

The manufacturer should be encouraged to redevelop the current risk analysis to bring subject the system to scrutiny under the more recent Risk Management standard (EN) ISO 14971.

[redacted]