

# **Q&A's RIVM report 'Silicone breast implants in the Netherlands, A market surveillance study'**

## **1. Why did the Inspectorate commission this study?**

The Inspectorate will periodically investigate medical devices. Because of the ongoing public debate about the safety of breast implants the Inspectorate commissioned RIVM to perform this study.

## **2. What did RIVM do?**

RIVM assessed the technical documentation of breast implants from manufacturers that were active on the Dutch market at the start of the investigation in 2014. Additionally, RIVM studied the composition of the silicone breast implants in the laboratory.

## **3. Do the materials used in the breast implants have harmful properties?**

RIVM performed laboratory analysis on the extent to which the implants have harmful properties. The laboratory analyses showed that the materials used in the products comply with an internationally accepted safety test used to determine harmful effects on cells. In order to verify biocompatibility of the product as a whole additional tests are required.

## **4. What was the result of the chemical analysis of the breast implants?**

RIVM performed laboratory analysis on the chemical composition of the breast implants. This analysis showed that two manufacturers have used a starting material that differs from the type declared in their technical files. In both cases medical grade silicone was used, therefore this finding does not have any consequences for the health of patients. In one implant relatively high concentrations of impurities (cyclosiloxanes) were found. On the basis of the results of earlier studies, among which the SCENIHR investigation in response to the PIP case, these anomalies are not expected to have any negative effect on patient safety.

## **5. What are cyclosiloxanes?**

Cyclosiloxanes are used as a raw material in the production of silicone. During production, it is normal that some residual cyclosiloxanes remain present in the silicone. In medical grade silicone such residual cyclosiloxanes are almost completely removed.

## **6. What is the involved health risk?**

The laboratory analysis of the implants showed no anomalies that could cause health damage. The deviations in the technical files are not expected to have any negative effect on patient safety.

## **7. I have breast implants of one of the investigated manufacturers, what should I do?**

The investigation of the RIVM did not show any anomalies that may compromise the health of patients. It is not necessary to take any additional measures or to contact your doctor. For more information on silicone breast implants the Inspectorate refers to the following [webpage](#).

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