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Press release

Suspension of devices manufactured by Silimed

From: Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) and Accelerated Access Review (https://www.gov.uk/government/organisations/accelerated-access-review)

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CE certificate for all medical devices made by Brazilian manufacturer Silimed suspended.

Medicines & Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) jointly with European healthcare product regulators of member states has been informed of the suspension of the CE certificate for all medical devices made by the Brazilian manufacturer Silimed. The German notified body, has recently carried out an inspection of the manufacturing plant in Brazil and established that the surfaces of some devices were contaminated with particles. The devices covered by the suspended CE certificate are implants for:

- silicone implants for plastic surgery: implants: breast implants, pectoral implants, gluteal implants, calf implants, implants for hand surgery, tissue expanders, facial implants, nostril retainers, suspension sheets for breast surgery
- bariatric surgery: gastric bands and balloons
- implants for urology: testicular implants, penile implants, vesical conformers, periurethal constrictors, tubes for hypospadias, vaginal stents
- silicone implants for general surgery: blocks and sheets
- silicone invasive devices: sizers for silicone implants

MHRA is investigating in collaboration with other European regulators and recommends that none of these devices should be implanted until further advice is issued.

We emphasise that for the moment there has been no indication that these issues would pose a threat to the implanted person’s safety. EU health regulators have initiated testing of samples of products to establish if there are any health risks.

In general, a medical device cannot be marketed in Europe without carrying a CE mark of conformity. A CE mark is applied by the manufacturer and means that the device meets the relevant regulatory requirements and, when used as intended, works properly and is acceptably safe. CE marking for a device is a claim of compliance with the essential requirements of European Directives. We continually monitor the safety of all medical devices.

MHRA Director of Devices, John Wilkinson said:

> " There has been no indication at this time that these issues would pose a threat to patient safety.
>
> We are urgently investigating this issue and are working closely with our European counterparts to decide whether there is any risk to health.
>
> In the meantime we would recommend that people who have questions about their implants should seek advice from their implanting surgeon or clinic."

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes NIBSC and CPRD. The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health.

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