Association of
British Healthcare Industries

Suspension of medical devices manufactured by Silimed

24 September 2015, UK – ABHI, the UK's medical technology industry association, is aware that CE certification for all medical devices produced by the Brazilian manufacturer Silimed has been suspended.

This decision was made after an inspection of its Brazilian manufacturing plant by a Notified Body[1], which found contamination on the surfaces of some devices.

ABHI welcomes the continuing work of Notified Bodies to uphold and enforce high European Union medical device safety standards through their audits of global device manufacturers. ABHI remains in support of such investigations.

European Union Medical Device legislation and standardisation has been responsible for the delivery of safe products and treatments to patients for over 20 years, with patient safety being of paramount importance to both regulators and manufacturers. Many millions of medical devices continue to be used across the EU everyday with few reports of failure.

ENDS

Notes to editors

1. A Notified Body is an organisation that has been designated by an EU member state (the designating authority) to assess whether manufacturers and their medical devices meet the requirements set out in legislation. https://goo.gl/0WLtq2

About ABHI

The Association of British Healthcare Industries (ABHI) is the industry association for the medical technology sector in the UK. ABHI's mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes. With over 250 members, ABHI leads the advocacy of the industry in order to advance access to medical technology. Our membership includes some of the leading multinational businesses in the sector in the UK right the way through to small and medium sized enterprises. For further information, visit the ABHI website (www.abhi.org.uk).

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