

Press release: Aquilon Medical

Nebulisers: people urged to stop use immediately

Following withdrawal of CE certification for the Aquilon series of nebulisers, the manufacturer has continued to place the nebulisers on the market. We have issued a [Medical Device Alert](#) today to all relevant healthcare professionals.

The affected nebulisers and packaging do have a CE mark placed on them, however this has not been obtained through appropriate regulatory oversight and therefore, their safety cannot be assured.

A medical device cannot be marketed in Europe without carrying a CE mark. It 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.

This issue affects Aquilon2, Aquilon, Aquilon+ and Aquilon Pro series medical nebulisers manufactured since 01 April 2015. MHRA believes that more than 8,000 Aquilon nebulisers, which have been on the market since 2015 are affected in the UK.

If there is suspicion that a nebuliser is affected, people are advised to stop using immediately, dispose of the device and to use an alternative nebuliser where available. It is advisable that you speak to your healthcare professional or GP who can help you find out if your device is affected, give you advice on how to dispose of it and provide a replacement.

John Wilkinson, MHRA's Director of Medical Devices said:

We have been made aware that the manufacturer has continued to sell nebulisers even after their CE certification was withdrawn. We cannot guarantee they have been manufactured to an appropriate standard.

These devices deliver potential life-saving treatment and it is vital they operate correctly when needed.

We are taking action, as a matter of priority, to make sure people are aware the CE mark has been withdrawn and that these devices should not be used and should be disposed of.

Patient safety is our highest priority and we urge anyone with questions to speak to a healthcare professional as soon as possible.