MHRA Device Safety Information

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Counterfeits and unbranded copies of LifeVac anti-choking devices may fail to work correctly or worsen choking incidents if used.

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 25 February 2024. The original webpage can be accessed here.

Summary

Anti-choking devices are intended to alleviate choking incidents after Basic Life Support protocols have been attempted and failed. There are numerous counterfeit and unbranded anti-choking devices being sold in the UK online which do not have a valid UKCA or CE mark and may pose a significant risk of worsening choking if used. These devices should not be used in the event of a choking emergency and should be disposed of once identified as counterfeit or non-compliant.

Action

1. Direct this notice to all appropriate managers, staff and users

2. Check that your anti-choking device is genuine using the provided guidance. Do not use the anti-choking device in the event of a choking emergency if you suspect that the device you have purchased is a counterfeit or unbranded copy of the legitimate LifeVac anti-choking device. This is because the device is not compliant with the UK Medical Device Regulations 2002 and therefore there is a significant risk the device may fail to work or even worsen the situation.

3. If you identify one or more of the above indicators of a counterfeit or unbranded anti-choking device copy, however are not certain, the MHRA would recommend contacting the legal manufacturer LifeVac Europe Ltd. The manufacturer can verify the legitimacy of the purchased product against their records of authorised distributors and product serial numbers.

4. The MHRA recommends that purchasers of counterfeit or unbranded anti-choking devices dispose of the device rather than returning the device to the seller due to the risk of resale.

5. Users should exercise caution when purchasing anti-choking devices online. Purchase only from reputable sellers and be particularly vigilant for sites using fake reviews to promote their product. Users may check that the device's manufacturer is registered with the MHRA via the public access registration database. The MHRA recommends you also refer to its published guidance on buying medical devices for personal use.

6. If you have previously used one of these counterfeit or unbranded anti-choking devices and it failed to work, please report the incident to LifeVac Europe Ltd and to IRIC (report an incident) providing information on where the device was purchased.

Actions for healthcare professionals

These actions are for healthcare professionals, especially health visitors or those working with parents in the community:

7. When advising parents regarding infant first aid or CPR, if questions are raised concerning the use of anti-choking devices or it is made clear that they possess one, healthcare professionals should:

    - reiterate the need to apply established Basic Life Support protocols first. The manufacturer's instructions should clearly refer to this in genuine devices. If necessary, refer to MHRA guidance concerning anti-choking devices.

    - ensure parents to check their own devices against the information in this document to verify they do not possess a counterfeit or unbranded device and follow actions 2 to 6 above if they do.

Device details

Counterfeit and unbranded anti-choking devices appear similar in design to the LifeVac anti-choking device, and primarily originate from China. No genuine anti-choking devices marketed in the UK are manufactured in China, and therefore products shipped from China should be treated with significant suspicion.

Image comparison between genuine and counterfeit anti-choking devices is provided further in the appendix. Key distinctions between a genuine and counterfeit device are highlighted.

Background Information

The MHRA is aware of numerous unbranded and counterfeit anti-choking devices (also known as airway clearance devices, choking rescue devices, or emergency first aid devices) which do not comply with the requirements of the UK Medical Device Regulations 2002 (UK MDR 2002) being sold online via marketplaces and drop-shipping websites.

The MHRA is currently aware of only two anti-choking device brands, LifeVac and Dechoker, which have a valid UKCA or CE mark and are registered with the MHRA in accordance with the UK MDR 2002. Both of these brands are intended to be used only after established Basic Life Support protocols (back slaps, abdominal thrusts) have been attempted and failed. There is further information and guidance on anti-choking devices available.

The vast majority of counterfeit and unbranded anti-choking devices, primarily originating from China, appear similar or identical in design to the LifeVac anti-choking device and, in some cases, may claim to be this brand.

Use of a counterfeit or unbranded anti-choking device carries a significant risk of failure to work and may even worsen the situation by further pushing obstructions down the airway passage due to their poor design and quality.

Suggested onward distribution (may not include all affected departments)

Healthcare
Ambulance Services
Community Care
District Nursing
Health & Safety
Health Visitors
Hospices
Maternity
Practice Nurses
Resuscitation Teams
Risk Management
Supplies/Procurement

Social care
Adult Care Services
Adult Day Services
Adult Residential Services
Care Homes
Children's Residential Services
Health, safety and wellbeing
Home Care services
Special Schools

Stakeholder engagement

The MHRA is continuing to work with online marketplaces to identify non-compliant listings as soon as possible and remove these products from sale. It is also working with them to prevent further listings from being made.

The MHRA has engaged with the following stakeholders in formulating the information:
- NHS England
- Northern Ireland Adverse Incident Centre
- NHS Scotland – Incident Reporting & Investigation Centre

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure NHS National Services Scotland, Tel: 0131 275 7575, email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

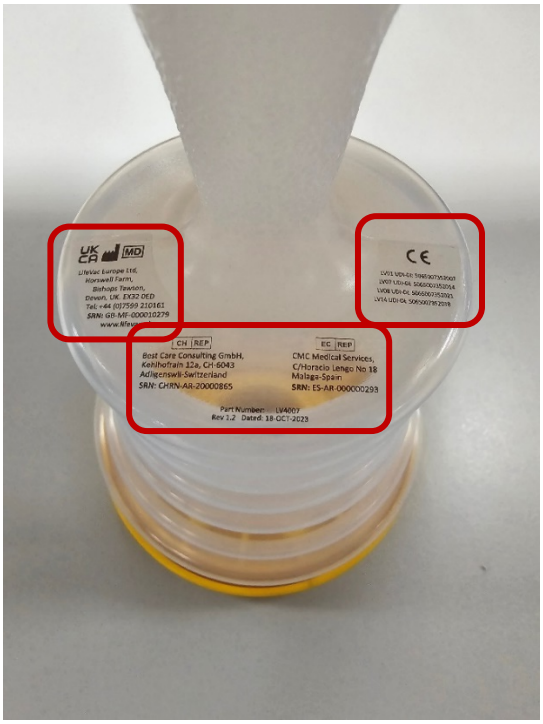
IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

To find safety alerts:
scan the QR code or click this link to visit our website

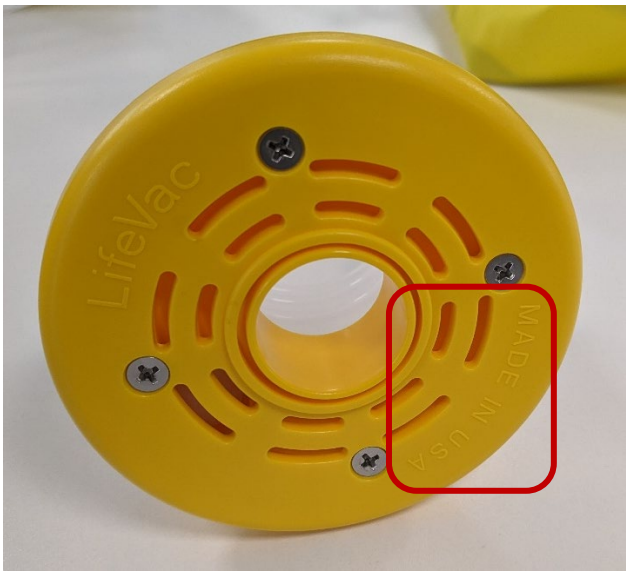
To report an incident:
scan the QR code or click this link to visit our website

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/

Appendix

Genuine LifeVac	Counterfeit or unbranded device
	
Look for the following on the device: - the UKCA or CE mark - name and address of the legal manufacturer - name and address of the EU authorised representative - Unique Device Identifier (UDI) numbers	The counterfeit or unbranded devices do not have these details. All these details are required to be present on the device where possible to meet the labelling requirements of the UK MDR 2002.
	
The LifeVac design incorporates a black one-way suction valve inside the bellows (or chamber) to prevent air being expelled on depression, so that only upward force is generated to remove obstructions from the airway.	The counterfeit or unbranded devices lack any form of one-way suction valve, meaning that air may be expelled from the device upon depression. This creates a downward force that potentially pushes obstructions further down the airway.

The base of a genuine LifeVac device does not include the ‘Made in USA’ statement as present on the counterfeit or unbranded devices.



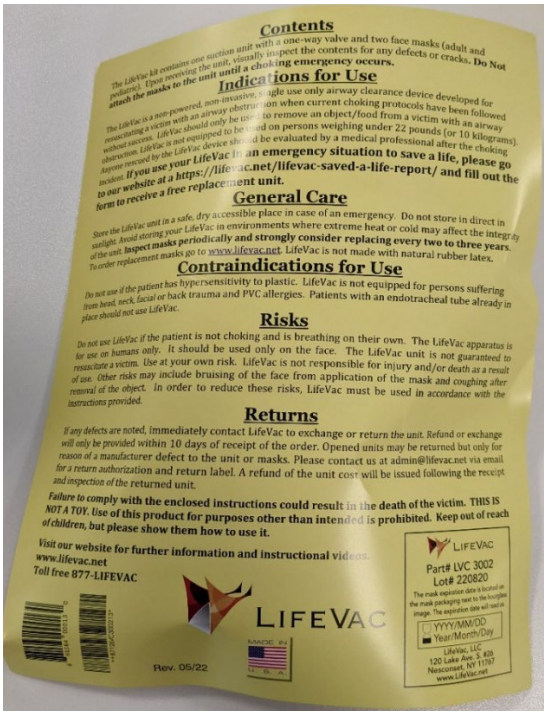
This is the base of a counterfeit or unbranded device, which does have ‘Made in USA’ embossed. This should not be present on genuine LifeVac devices.

Packaging of anesthesia masks supplied with the genuine LifeVac device include details of their legal manufacturer and EU authorised representative.

Though the masks included with the genuine device are originally manufactured in China, the device as a whole does not originate from China.

Packaging of anesthesia masks supplied with the counterfeit or unbranded devices includes some relevant detail. For example, CE marking and batch numbers are displayed, but not the manufacturer and EU Authorised Representative (EC Rep) details.

The genuine LifeVac device is supplied with a full instructions manual booklet as pictured. This includes UKCA or CE marking and bears the relevant legal manufacturer details for the UK market, LifeVac Europe Ltd.



The counterfeit or unbranded devices are supplied with a single card of instructions, or numerous single page inserts. These are not the appropriate instructions intended for the UK market and have not originated from LifeVac LLC as presented. The instructions lack UKCA or CE marking which should be present according to the labelling requirements of the UK MDR 2002.