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EU Must Crack Down Harder On Fake Medical Devices, Says Innovator

by [Natasha Barrow](#)

Counterfeit copies of LifeVac Europe's anti-choking devices have been registered on the EU's EUDAMED database and continue to be sold on third-party platforms. *Medtech Insight* asked director of sales and marketing Matthew Banagan how the company deals with fake devices and what the authorities must do.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) believes that over 10,000 counterfeit anti-choking medical devices, identical in design to those of UK-based manufacturer LifeVac Europe, have been sold to the public through third-party platforms within the last two years.

The genuine LifeVac, a noninvasive airway clearance medical device, has saved over 1,987 lives since 2012, said LifeVac Europe. But the presence of counterfeit products has presented serious danger to the public, the company said.

"There are thousands of these [fake] devices in the hands of the general public. They are ticking time bombs," Matthew Banagan, LifeVac Europe's sales and marketing director, told *Medtech Insight*.

Insufficient regulatory oversight and a lack of third-party seller responsibility are hindering a proper crackdown on falsified medical devices.

[A survey](#) released by the Council of Europe in late 2023 found that EU member states lacked detailed and sufficient guidance on the responsibilities and procedures for falsified medical devices.

The Medical Device Regulation provides oversight of falsified medical devices in Europe. However, some countries have contested that its provisions are insufficient. (Also see "[European](#)

[Member States Call For Direction On Falsified Medical Devices](#) - Medtech Insight, 16 Jan, 2024.)

Companies like LifeVac Europe have the burden of detecting and reporting fakes being distributed via online marketplaces and dropshipping websites.

“They [third-party platforms] don’t have procedures in place. They don’t ask for proof that the device is genuine,” said Banagan.

The result is consumers can directly purchase fake devices, believing they are the genuine product.

Fake LifeVacs Registered On EUDAMED

EUDAMED, the EU database on medical devices, is described as a key instrument in the “fight against falsified medical devices” in the MDR. (Also see "[European Member States Call For Direction On Falsified Medical Devices](#)" - Medtech Insight, 16 Jan, 2024.)

But Banagan told Medtech Insight, “One of the counterfeit products sold on Amazon EU was registered on EUDAMED.”

The counterfeit LifeVac devices are almost identical in design to the genuine product, but don't meet the necessary regulatory and quality standards. The fake devices that were registered on EUDAMED used a CE declaration for anesthesia masks. The anesthesia masks used with the LifeVac airway clearance devices are manufactured separately, and by a different provider, meaning they have a separate declaration.

Medtech Insight asked EUDAMED to clarify how this situation occurred.

EUDAMED replied: “The registration of economic operators in EUDAMED is restricted and has to be approved by a competent authority. When registering devices, the economic operators are using already existing data from their declaration of conformity and their device certificate(s).”

It continued: “The registration of ‘fake’ medical devices should therefore not be possible in EUDAMED, but if this should occur, any registration can easily be linked to a company and legal actions can be taken by the authorities.”

“For me personally, it’s [EUDAMED] a waste of time. It’s optional [...] and not fully functional yet,” Banagan said. EUDAMED remains in development, and the modules so far completed are voluntary. (Also see "[Commission Proposes To Extend IVDR Transition Periods And Launch Eudamed Sooner](#)" - Medtech Insight, 24 Jan, 2024.)

Fake Devices Are Identified Too Late

Consumers complain when they test a product and find that it does not work, Banagan claimed. “That’s how we have uncovered fakes,” he said.

“Every single week, I do a search [for fake LifeVacs] and send my findings to the MHRA,” said Banagan. He is critical that fake medical devices that have already reached the consumer are being identified too late.

Banagan’s experience is not unique. Many European countries report difficulties in detecting fake devices, the survey found. Customs, supply chain stakeholders and healthcare practitioners have reported these challenges.

However, the fake products do not have the necessary contact, identification and traceability data that genuine devices carry.

The MHRA stressed counterfeit products do not have UKCA, CE mark, or Unique Device Identifier (UDI) details printed on them. The lot numbers are incorrect and do not contain the proper sequence of letters and numbers, it said. The MHRA has issued a complete list of differences in the [Device Safety Information](#).

Anti-choking devices were made available for purchase by the general public in June 2023. Although now classified as a class I medical device, before June 2023 LifeVac Europe’s device could only be used by healthcare professionals trained in advanced life support, or only after Basic Life Support protocols had failed. This was because the devices fell outside of the UK’s Basic Life Support protocols and resuscitation guidelines.

Complex Chain Of Falsified Medical Device Oversight

In the EU, member states have conflicting views on whether the MDR is sufficient to regulate falsified medical devices, according to the survey. (Also see "[European Member States Call For Direction On Falsified Medical Devices](#)" - Medtech Insight, 16 Jan, 2024.)

No single EU entity is responsible for detecting and reporting falsified medical devices. Instead, the responsibility is spread between national health authorities, customs, the police, manufacturers, supply chain stakeholders, healthcare providers and patients.

The relationship between all these entities appears to be complex, the survey found.

In the meantime, third-party selling platforms are not held accountable for what they do, Banagan, said, adding that fake LifeVac products can still be found on e-commerce sites, and “more keep popping up every day.”