

**Ministry of Health**  
Directorate General of Medical Devices and Pharmaceutical Services  
via Giorgio Ribotta 5  
IT - 00144  
Roma

13 May 2020

To whom it may concern,

It has come to our attention that medical devices we, Vyaire Medical, produce as the Legal manufacturer, namely Bellavista ventilators, which were sold into Asian countries, have now been re-sold/re-directed into hospitals and Institutions within the European Union without Vyaire involvement.

We have been informed of the volume and the serial numbers of the devices which have apparently been delivered into Italy as shown in the Table below.

Due to this re-direction we do not have full traceability of these devices, nor are we aware of the provenance of these devices and therefore we do not know where the devices have potentially been installed or where they are being used within your country.

The following is a list of devices which we understand are now within Italy that, whilst potentially bearing the CE mark on their label would not be properly CE marked with full approval for the European Union:

Product	Quantity	Serial Number	Organisation Vyaire sold to
BV1000	1	MB 202150	Tokibo Company (Hong Kong) Limited
	1	MB 202144	
	1	MB 202200	
	1	MB 202147	
	1	MB 202521	
	1	MB 202526	
	1	MB 202536	
	1	MB 202528	
	1	MB 202525	

We are concerned that these devices have not been reviewed for effectiveness and/or installed by Vyaire Medical engineers.

Traceability has been lost and CE approval measures have not and cannot be maintained. Also Instructions for use may not be in the appropriate language as they will potentially be in the original receiving country's language. We therefore cannot confirm the provenance of these devices.



We understand that this may have occurred as a direct response to the Covid19 Pandemic, but we need to make you aware that these devices were not intended for the EU market and therefore may not meet all existing and relevant requirements.

Would this be appropriate to be filed as a Vigilance report through your systems?

Yours faithfully

A handwritten signature in black ink, appearing to read "P. J. Bates".

**Phillip J Bates**

**RA/QA Director**

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