

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

24 April 2020

To whom it may concern,

It has come to our attention that medical devices we, Vyaire Medical, produce as the Legal manufacturer, namely Vela ventilators, which were sold into Asian countries, have now been re-sold/re-directed into hospitals and Institutions within the European Union.

We have been informed of the volume and the serial numbers of the devices which have apparently been delivered into Italy by the organisation 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 Non-CE marked devices, which we understand are now within Italy, with their serial numbers, quantity, Organisation delivered by and the Organisation provided from:

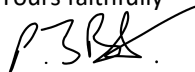
Product	SKU	Quantity	Serial Number	Organisation delivered by	Organisation provided from	Rational
VELA STD	16530-14	1	CAT01139	Shandong Beilai Medical Co.	Shandong Yanzhou hospital	Hospital donated to Italy
		1	CAT01166			
		1	CAT01186			
		1	CAT01197			
		1	CAT01198			
		1	CAT01180			
		1	CAT01202			
		1	CAT01208			

We are concerned that these devices are **not** CE certified devices for use within the EU and they have not been approved for emergency use within the EU nor have they been reviewed for effectiveness and/or installed by Vyaire Medical engineers.

We understand that this may have occurred as a direct response to the Covid19 Pandemic, but need to make you aware that these devices are 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



Phillip J Bates
 RA/QA Director
Phillip.bates@vyaire.com