imtmedical	**FORM Field Safety Notice (FSN)**

URGENT FIELD SAFETY NOTICE
Diagnostics Package Pulse Oximetry (Adult/Pediatric)
Diagnostics Package Capnography (Mainstream)
for bellavista™ ventilators
Incorrect CE Marking
for Field Safety Corrective Action FSCA-2021-002 – Recall

23 December 2021 FSN Ref: FSCA-2021-002-FSN-1

Attention: Distributors and users of the bellavista™ ventillators and their accessories.

Dear Customer,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by imtmedical ag, as part of Vyaire Medical, a recall limited to two accessories for bellavista™ ventilators where the CE mark was placed on the products in error.

Details on affected devices

The accessories affected by this recall are stated in the following table:

Affected Product	Part Number
Diagnostics Package Pulse Oximetry Adult/Pediatric	301.113.000
Diagnostics Package Capnography Mainstream	301.114.000

Description of the problem

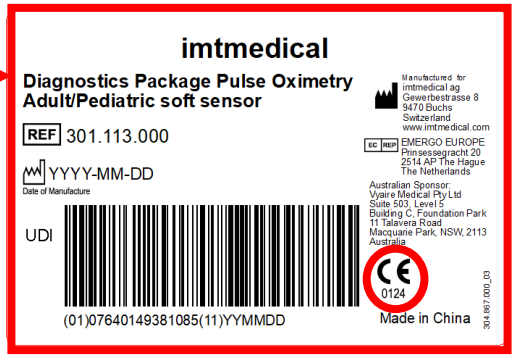
Product labeling error: Notified Body number placed in error on the product CE mark
It has come to our attention that the CE mark with the Notified Body number (0124) of DEKRA Certification GmbH, was placed in error on the outer packaging of the two accessories for the bellavista™ family of ventilators listed above. Consequently, the products do not fulfill labelling compliance requirements, and therefore, imtmedical ag is removing them from the market. There is neither impact to actual use of the product nor a product safety concern. This is an issue of labelling non-complaince.

How to identify affected products

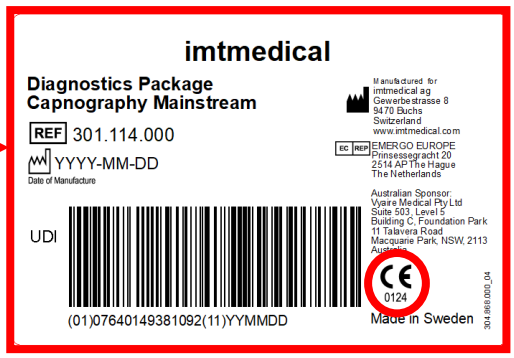
Any affected labels are located on the outer packaging.

To enable identification of affected products, pictorial depictions of samples of the affected labels on the outer packaging are provided as follows:

- **301.113.000**



- **301.114.000**



Actions to be taken by distributors:

- Check receipt and contents of the FSCA package (this *FSN*, the *End User Response Form* and *Distributor Response Form)*.
- All distributors of the affected products shall read and take into consideration all instructions and information provided in this *FSN*.
- If you have further distributed affected product(s) to other persons or facilities, promptly forward a copy of this *FSN* and *End User Response Form* (**FORM Field Safety Corrective Action (FSCA) End User Response)** to those recipients and complete the *Distributor Reponse Form* (**FORM Distributor Field Safety Corrective Action (FSCA) Response**) and return it to **GMB-AMS-FSCAresponsecentre@vyaire.com.**
- Inspect current inventory on-hand. A 100% physical inventory should immediately be performed to identify and remove affected product(s) from commercial distribution due to the identified labelling issue.

Actions to be taken by the users:

- Check receipt and contents of the FSCA package (this *FSN* and the *FSCA End User Response Form)*.
- All users of the affected products shall read and take into consideration all instructions information provided in this FSN.
- Identify affected product(s) as described above under “How to identify affected products.”
- Inspect current inventory on-hand. A 100% physical inventory should immediately be performed to identify and remove affected product(s) from distribution and use due to the identified labelling issue.
- Fully complete the attached *End User Response Form* (**FORM Field Safety Corrective Action (FSCA) End User Response)** and return it to **GMB-AMS-FSCAresponsecentre@vyaire.com**.
- We respectfully request to receive the fully completed and signed *End User Response Form* **no later than January 7th, 2022**.

Product returns for credit

We will contact you on receipt of the fully completed and signed *End User Response Form* (**FORM Field Safety Corrective Action (FSCA) End User Response)** regarding the arrangement of product return and reimbursement.

Contact Information

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA or to related Forms, please email **GMB-AMS-FSCAresponsecentre@vyaire.com.**

The undersigned confirms that this FSN has been notified to the appropriate Regulatory Agencies.

Sincerely,

Abir Roy
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