bluepoint medical GmbH & Co. KG
medical · safety · diagnostic
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Selmsdorf, 11th August 2020

Dear Viamed team,

we wish to notify you of a quality issue identified within the flow-sensor product manufacturing processes. The issue is related to the flow-sensor body part; wherein our internal Quality Control found intermittent issues of leakage failure.

Investigation revealed that the cause of the issue is employee error with impact on flow-sensors manufactured from Mid-May 2020 until end of July 2020. The following products are potentially affected:

REF: 1030132000 (SpiroTrue H – Box of 6 pcs.)

LOT: 2006-1026-H (420 boxes) / 2007-1027-H (36 boxes) / 2007-1028-H (164 boxes)

Risk Evaluation:
Due to the massive leakage the faulty flow-sensors will be identified during the ventilator set-up/self-test before use on the patient. The issue is therefore classified as not critical to the end-user.

Corrective Action:
We advise you to return the above-mentioned products for re-work at Bluepoint Manufacturing or replacement.

Our flow-sensor product manufacturing processes have been reviewed and additional test steps and training were introduced which prevent future repetition of the issue.

We sincerely apologize for the inconvenience caused due to this issue and assure you that we do the utmost to deliver products of highest quality to you.

Sincerely,

Bernd Lindner

Managing Director