



Date: 30th May 2022

Customer Name  
Mr. A. B. Addressee  
PO Box/ street

**Re: ISO 18562 Biocompatibility Evaluation Requirements – Philips Additional Lines Impacted**

Dear Valued Philips Customer,

Since our last communication on 13<sup>th</sup> May 2022 regarding ISO 18562 regulatory hold, Philips have identified a further 49 (SRC & HRC) products that are also impacted by the ISO. Philips teams are working with urgency to resolve the situation, whilst also ensuring the latest communication contains all impacted products. If there are any further product families included as part of the impacted list, Philips will communicate with speed, however due to the ISO taking effect 1<sup>st</sup> April, there is a low risk of any large increases to the total list.

As a reminder, It is important to highlight that the regulatory hold on new orders is due to the ISO 18562 validation requirement and is not related to a quality issue.

Please see below link to the NHSSC ICN, which will be updated periodically. The additional 49 impacted products are visible within the downloads section;

<https://www.supplychain.nhs.uk/icn/supply-issues-philips-healthcare-respironics-niv-and-sleep-therapy-and-respiratory-solutions-products-multiple-products/> - NHSSC ICN number 1608.

We regret the impact this may have on your Trust and the inconvenience it may cause your patients. We are working to complete this required validation on as many products as quickly as possible so we can release these products back to the market for normal sale, but in the interim, we are grateful for NHS Supply Chain's support to maintain national supply where possible.

If you have any questions, or if there are other ways we can support you, please contact your Philips Respironics representative.

Sincerely,  
Steve Vitue  
Commercial Leader SRC UKI

