

July 2, 2020

To Whom It May Concern

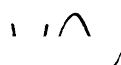
This letter is to confirm that the shelf life of GAMMEX® Latex Ortho surgical glove is 3 years. The provisional shelf life claim of the glove was determined via accelerated aging studies in compliance with EN 455-4 (Medical Gloves for Single Use – Requirements and Testing for Shelf Life Determination). In parallel with the accelerated aging study, Ansell has initiated a real-time aging study to confirm the provisional shelf life.

All testing data and documentation pertaining to shelf life studies are maintained by Ansell and all records are filed as part of the technical documentation. Below is a summary of the results:

- All studied lots demonstrated a force at break above the minimum 9N required by the EN 455-4 and EN 455-2 standards
- All studied lots met the acceptable criteria for freedom from holes in accordance to the EN 455-4 and EN 455-1 standards.
- The glove packaging met the predetermined requirements for pack integrity tests as per the EN 455-4 standard.

Based on the outcome of the shelf life study, the GAMMEX® Latex Ortho product, made in Malaysia, are commercialized with the expiry date of 3 years and fit for the intended purpose as a surgical glove.

Please reach out to the undersigned for further information or clarification.

Yours sincerely, 



Khor Siek Meng
Senior Director,
Ansell Quality Assurance HGBU
Email: siekmeng.khor@ansell.com

4th-Feb-2021

Date