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Change Notification

Affected product	A074 (Polyclonal antibody to human blood coagulation factor XIII (B-subunit))
Change description	New packing unit of A074 is 500 µg/vial instead of 200 µg/vial.
Reason	As part of our ongoing quality oversight, a deviation in the protein determination was identified for the first and so far only batch of A074. Following a thorough assessment, it was determined that the actual antibody content (protein concentration) was approximately twice as high as originally indicated.
Measures	<p>To ensure consistent product quality and to guarantee that customers receive the amount of antibody they have received in the past, a corrective action has been implemented: the fill quantity has been increased to 500 µg.</p> <p>This adjustment ensures that all future units reliably contain the antibody amount customers are accustomed to. The change has been evaluated and approved in accordance with established change control procedures.</p> <p>All relevant processes and documentation have been updated accordingly. The change control process has been completed.</p> <p>The new packaging unit for A074 is 500 µg per vial; the price remains unchanged.</p> <p>This change notification will be communicated to customers and implemented on the website.</p>
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Note	This document is valid without a signature.