


CHANGE NOTIFICATION

Notification number	PZ_2403_01	Date	2024.03.25
Change number	078		
Subject of the change	Classification and labelling change. Way of delivering assigned values change.		
Affected products	Cat. No	Product name	
	n/a	G-CAL	
Change category	<input type="checkbox"/> raw materials <input type="checkbox"/> quality control <input type="checkbox"/> packages <input checked="" type="checkbox"/> information provided with the product <input type="checkbox"/> manufacturing <input type="checkbox"/> final product <input type="checkbox"/> other		
Change description	<ul style="list-style-type: none"> The classification and labelling of G-CAL have been changed. The current labelling below: <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Warning</p>  <p>H315 Causes skin irritation. H319 Causes serious eye irritation. P280 Wear protective gloves, protective clothing, eye protection or face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> </div> The way of delivering assigned values for G-CAL has also been changed. Since implementation of this change, the assigned values will no longer included in instruction for use and they will be presented in the value sheet. 		
Reason for change	<ul style="list-style-type: none"> Fulfilling the requirements of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 taking into account Adaptation to Technical Progress (ATP) to the CLP Regulation. Optimization of assay sheet preparation or updating process. 		
Implementation	May 2024		
Additional information	<p>The above changes will be implemented from lot number GC0524.</p> <p>The changes does not affect the performing of determination, functionality and stability of the calibrator.</p> <p>Using calibrator wear personal protective equipment and follow the new classification of the calibrator.</p> <p>When the G-CAL lot GC0524 will be on sale, an updated material safety data sheet (MSDS) will be available at: https://cormaydiagnostics.com/customer-support/documents.</p>		
Attachments	n/a		

If there are any questions or concerns with respect to this change, please feel free to contact your Area Sales Managers.

Quality Assurance Manager