

CHANGE NOTIFICATION

|                            |   |  |            |
|----------------------------|---|--|------------|
| <b>Notification number</b> | <b>PZ_2309_03</b>   | Date   | 21.09.2023 |
| Change number              | 111   |  |            |
| Subject of the change      | Change of shelf life.   |  |            |
| Affected products          | Cat no  | Product name   |            |
|                            | 6-300   | CORMAY CRP ULTRA   |            |
|                            | 3-339   | CORMAY CRP ULTRA 60  |            |
|                            | 3-340   | CORMAY CRP ULTRA 120   |            |
|                            | 7-225   | ACCENT-200 CRP ULTRA   |            |
|                            | 7-325   | ACCENT-300 CRP ULTRA   |            |
|                            | 7-425   | A-400 CRP ULTRA  |            |
|                            | 7-847   | A-800 CRP ULTRA  |            |
|                            | 4-261   | PRESTIGE 24i CRP ULTRA   |            |
|                            | 4-480   | PRESTIGE 24i CRP ULTRA   |            |
|                            | 9-437   | OS-CRP ULTRA   |            |
|                            | 5-553   | B50-CRP ULTRA  |            |
|                            | B02-R0040   | EQ CRP ULTRA   |            |
|                            | 2-352_R1  | CORMAY CRP ULTRA BULK  |            |
|                            | 2-352_R2  | CORMAY CRP ULTRA BULK  |            |
|                            | 4-276   | CORMAY CRP ULTRA CALIBRATORS   |            |
|                            | 4-280   | CORMAY IgE CALIBRATORS   |            |
| 4-277                      | CORMAY RF CALIBRATORS   |  |            |
| Change category            | <input type="checkbox"/> raw materials<br><input type="checkbox"/> packages<br><input type="checkbox"/> manufacturing   | <input type="checkbox"/> quality control<br><input type="checkbox"/> informations provided with the product<br><input checked="" type="checkbox"/> final product<br><input type="checkbox"/> other |            |
| Change description         | In connection with the update of the Real Time Stability Report and Accelerated Stability Report it was decided to change the expiration date of reagents and calibrators listed above. Changed expiration dates of specific product's lots (from which these change will be implemented) can be found in Appendix No. 1.   |  |            |
| Reason for change          | Update of real time and accelerated stability studies reports.  |  |            |
| Implementation             | September 2023  |  |            |
| Additional information     | During transitional periods reagents and calibrators with different shelf life may be available for sale. <u>Expiration dates of products currently available on the market (with lot numbers different than listed in the Attachment 1) remain unchanged.</u> Changed expiration dates of specific product's lots can be found in Appendix No. 1.<br>The above change does not affect the performing of determination and functionality of products. |  |            |
| Attachments                | PZ_2309_03_Attachment_1 - List of kits affected by the changes.   |  |            |

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