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Italy

Vimodrone, June 09<sup>th</sup> 2017

SUBJECT: Compliance for USP tests

To whom it may concern

Test item: "FLON-CHEM 1121"

Studies performed: The following studies were performed in order to determine the biocompatibility of the product FLON-CHEM 1121 according to USP &lt;87&gt; and USP &lt;88&gt;:

**CYTOTOXICITY****(Elution Test according to USP <87>, Eurofins study No. S-2017-01006 SAM)****USP BIOLOGICAL TEST (CLASSIFICATION VI/121 °C)****(USP test according to USP <88>, Eurofins study No. S-2017-01243 SAM)**

Results: In the cytotoxicity test under the given conditions the cells treated with the test item extract showed no reactivity (grade 0), so the test item "FLON-CHEM 1121" must be considered not cytotoxic after 48 hours.  
The test item "FLON-CHEM 1121" meets the criteria of USP Biological Tests Classification VI/121°C.

Your sincerely,



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Project Manager & GLP Study Director – Medical Devices  
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**Eurofins Biolab S.r.l.**

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