

烟台赛普生物技术有限公司
CelluPro, Ltd.

中国（山东）自由贸易试验区烟台片区烟台开发区北京中路 60 号
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关于细胞培养基中乳胶的声明

Statement on Latex in Cell Culture Media

No: QS- 23 - 019

敬启者：

To whom it may concern:

接触天然橡胶与对天然胶乳蛋白过敏的个体的过敏反应有关，由某些天然存在的可溶性过敏原蛋白引起的，具体参考以下准则：

Contact with natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. This appears to be caused by certain naturally occurring soluble allergenic proteins. The following guidelines have been introduced:

美国食品药品监督管理局

The US Food and Drug Administration

1. 含有天然橡胶的器械用户标签（21 CFR 801.437）——2019 年 4 月 1 日。
User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437) -- 1 April 2019.
2. 工业和食品药品监督管理局工作人员指南-医疗产品标签建议，告知用户产品或产品容器不是用天然乳胶制成（2014 年 12 月）。
Guidance for Industry and Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex (December 2014).

欧盟委员会

The European Commission

1. 医疗器械指令（93/42/EEC）对含天然乳胶的医疗器械的影响：制造商和公告机构指南。MEDDEV 2.5/9 rev. 1（2004 年 2 月）。
Implications of the Medical Devices Directives (93/42/EEC) in Relation to Medical Devices Containing Natural Rubber Latex: A Guide for Manufacturers and Notified Bodies. MEDDEV 2.5/9 rev. 1 (Feb 2004).

特此声明，赛普生物的细胞培养基和包装材料不含有天然乳胶，且没有引入天然乳胶的风险。但产品在生产过程中可能会因生产技术人员使用的手套偶然接触到乳胶。

It is hereby stated that CelluPro's cell culture media and packaging materials do not contain natural rubber and there is no risk of introducing natural rubber latex. However, there is potential

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for incidental contact with latex from the gloves used by production technicians during the manufacturing process.

最终培养基产品未进行乳胶检测。

Testing for detection of latex in our final media is not performed.



Quality Assurance Department

2023-07-18