质量保证书 Quality Assurance Certificate

除菌级疏水聚四氟乙烯滤芯
Sterilizing-Grade Hydrophobic PTFE Filter Cartridge

产品 Product：GPFMP0022SSCM05SP
精度 Pore Size：0.22μm
批号 Lot No.：YT3QP43620
生产日期 Manufacture Date：2023-06-20
保存期限 Shelf Life：3 years

本文件用于证明科百特生产的过滤产品参照良好作业规范。
This document certifies that the product was manufactured by Cobetter in accordance with Current Good Manufacturing Practice standards.

该产品的开发，生产等过程符合 ISO9001 管理体系要求
This product is developed, produced and distributed according to the management system certified for compliance with ISO9001.

质量保证准则 Quality Assurance Criteria

以下为定期检测项目
The following items are checked on a regular basis:

✧洁净度 Cleanliness

该产品符合 21 CFR,section 210.3(b)(5)(6)和 211.72 中关于无纤维释放过滤器的规定。
This filter product complies with the title 21 CFR, section 210.3(b)(5)(6) and 211.72.

✧TOC 和电导率 TOC&Conductivity

经注射用水冲洗后，灭菌后滤芯冲洗水的 TOC 小于 500ppb （ USP<643> ），电导率小于 1.3 μS/cm @25℃（USP<645>）。
After pre-flushed with water for injection, effluent of the sterilized filter exhibited ＜500 ppb TOC meeting the requirements of USP<643>, and less than 1.3μS/cm @25℃ meeting the requirements of USP<645>.

✧细菌内毒素 Bacterial Endotoxins

采用凝胶法测试（USP<85>），每支滤芯洗脱液中内毒素含量低于 0.25EU/ml。
Aqueous extraction from a cartridge contains less than 0.25EU/ml as determined by *Limulus Amebocyte Lysate* (LAL), meeting requirements of USP<85>.

✧生物安全性 Biosafety

所有构成材料符合 USP<88>关于第 VI-121℃级塑料材料的生物安全性评价。
All materials of this filter meet the requirements of the current USP<88> for plastic classVI-121℃.

✧间接食品添加剂 Indirect Food Additive

所有构成材料符合 FDA 21CFR177-182 中关于间接食品添加剂的要求，所有构成材料符合欧盟 1935/2004/EC 关于食品接触材料的要求。如需更多的材料构成的信息，请联系科百特销售工程师。
All component materials meet the FDA Indirect Food Additive requirements cited in 21CFR177-182. All component materials meet the requirements of the EU regulation 1935/2004/EC. Contact Cobetter for more information about materials of construction.

✧非动物来源申明 Animal origin statement

基于目前从供应商处获得的信息，该产品的所有构成部分均为非动物来源物料。
Based on the current information from our suppliers, all component materials used in the manufacture of this product are animal-free.

✧灭菌耐受性 Thermal Stability

科百特验证数据 Cobetter SLS Center test data:

- 在线蒸汽灭菌 SIP: 100 正向（forward，ΔP≤30kPa） & 50 反向（reverse，ΔP≤10kPa） cycles of 30min,145℃
- 离线蒸汽灭菌 Autoclave: 400 cycles of 30 min,130℃

注：SLS 验证结果是基于对从未使用的新滤芯进行的反复灭菌能力测试数据。滤芯的重复使用次数以实际的工艺验证为准。
Note： The SLS (Science Lab Service) test data is based on new elements. The filter for repeated use must be based on the result of process validation.

✧最大压差 Maximum Differential Pressure

正向 Forward：
0.69MPa/25℃，0.4MPa/60℃，0.24MPa/80℃；
反向 Reverse：
0.3MPa/25℃，30min，0.1MPa/80℃，30min
注：滤芯不建议反向过滤使用。
Note: Reverse filtration is not recommended.

批放行准则 Lot Release Criteria

该产品批次按质量保证体系的原则进行的抽样、测试及放行。
This manufacturing lot was sampled, tested and released by quality assurance.

✧完整性测试 Integrity Testing

每支膜滤芯出厂前都经过以下测试合格并放行。
Each membrane filter cartridge passed the following tests before release, the Integrity test standard are as follows:

完整性测试标准 Integrity Test Standard（20℃）：
泡点 Bubble Point(BP): ≥0.1MPa(60 : 40 (v/v) IPA : Water)
扩散流 Diffusion Flow(DF):≤12ml/min/5"@95kPa(60 : 40 (v/v) IPA : Water)
水侵入 Water Flowrate Test(WFT):≤0.38ml/min/5"@0.25MPa

除菌级滤芯的完整性测试与 ASTM F838 细菌挑战结果相关联，该细菌挑战测试方法符合 cGMP 无菌药品生产指南（2004 年 9 月发布）的相关要求。
For sterilizing grade filters, these integrity test values have been fully correlated to the ASTM F838 Bacteria Challenge test (LRV/cm²≥7) , in conformance with the requirements of the FDA Guideline about Sterile Drug Products Produced by Aseptic Processing according to Current Good Manufacturing Practice (September 2004).

Martin Quality Assurance, Cobetter
UM5101 Rev. 06

cobetter®
filtration

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