

附件 1

医疗器械召回事件报告表

提交：□企业所在地省级食品药品监督管理部门

■器械注册/备案部门

产品名称	颅内压探头	注册证或备案 凭证编码	国械注进 20153072680
生产企业名称	法国索菲萨		
代理人名称	北京美科创新科技有限公司		
召回单位负责人和联系方式，经办人和联系方式	负责人：蒋炜 010-87194288 经办人：赵少娟 010-87194288		
产品的适用范围	该产品 与 SOPHYSA 颅内压监测仪配合，由经过专业训练的人员操作使用，用于颅内压测量。其中，PSO-VT 和 PSO-VTT 型号产品可同时进行脑脊液引流。		
涉及地区和国家	全球	召回级别	一级召回
涉及产品生产（或进口中国）批次、数量	共 5922 件、共 5922 件	涉及产品 型号、规格	PSO-VT, PSO-VTT
识别信息 (如批号)	设备序列号，请见附表	涉及产品在 中国的销售数量	共 4393 件
召回原因简述	收到关于颅内压探头漏液的投诉，经过深入调查分析，确定泄漏的风险与探针嵌入导管的制造过程偏差有关。确定相关潜在受影响的批次拟对相关批次产品采取主动召回。漏液均在植入过程中发现，		

	并立即更换了相关探头。因此，收到的投诉未对患者有任何伤害； 如果在植入过程中漏液未被发现，可能会对患者造成感染风险。
纠正行动简述（包括召回要求和处理方式等）	发起召回行动；向受影响客户发放主动召回通知书，请客户知晓并注意此问题；退回涉事产品并更换新产品。

报告单位：北京美科创新科技有限公司（盖章）

负 责 人：蒋 炜

报 告 人：赵少娟

报告日期：2024 年 5 月 8 日



附表：受影响颅内压探头规格型号及序列号信息

共 5922 件颅内压探头受到该问题影响，其中

规格型号：PS0-VT，2887 件

规格型号：PS0-VTT，3035 件

规格型号及相应的序列号信息请见以下：

型号：PS0-VT，设备序列号清单如下：

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