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	电子血压计	注册证或备案凭证编码	国械注进20172072361
生产企业名称	InBody Co.,Ltd.		
代理人名称	拜斯倍斯医疗器械贸易（上海）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：林茜　　联系方式：021-64439705 经办人：詹颜嘉　　联系方式：021-64439705		
产品的适用范围	该产品在体外测量并显示成人的血压(收缩压、舒张压)和脉搏率。		
涉及地区和国家	中国	召回级别	三级
涉及产品生产（或进口中国）批次、数量	240台	涉及产品型号、规格	BPBIO320

识别信息（如批号）	SN： B822005172 B822005353 B822005334 B822005338 B822005356 B822005303 B822005295 B822005247 B822005265 B822005245 B822005241 B822005211 B822005262 B822005271 B822005285 B822005217 B822005263 B822005311 B822005304 B822005335 B822005171 B822005355 B822005307 B822005281 B822005273 B822005352 B822005360 B822005292 B822005344 B822005362 B822005369 B822005341 B822005214 B822005357 B822005345 B822005212 B822005266 B822005213 B822005218 B822005267 B822005361 B822005368 B822005219 B822005264 B822005261 B822005370 B822005286 B822005248 B822005283 B822005243 B822005279 B822005239 B822005222 B822005306 B822005278 B822005340 B822005342 B822005291 B822005284 B822005282 B822005308 B822005312	涉及产品在中国的销售数量	236台

	B822005310 B822005277 B822005336 B822005343 B822005358 B822005221 B822005301 B822005314 B822005150 B822005146 B822005260 B822005145 B822005227 B822005380 B822005232 B822005376 B822005332 B822005148 B822005378 B822005359 B822005337 B822005313 B822005242 B822005153 B822005151 B822005209 B822005149 B822005194 B822005244 B822005215 B822005302 B822005183 B822005305 B822005379 B822005339 B822005354 B822005300 B822005189 B822005309 B822005147 B822005191 B822005192 B822005195 B822005152 B822005180 B822005216 B822005181 B822005274 B822005173 B822005253 B822005175 B822005186 B822005252 B822005193 B822005190 B822005275 B822005184 B822005280 B822005178 B822005225 B822005174 B822005179 B822005228		

	B822005237 B822005223 B822005224 B822005255 B822005272 B822005367 B822005249 B822005372 B822005269 B822005258 B822005366 B822005176 B822005226 B822005371 B822005373 B822005177 B822005276 B822005250 B822005254 B822005296 B822005363 B822005231 B822005182 B822005289 B822005348 B822005235 B822005328 B822005287 B822005326 B822005325 B822005375 B822005290 B822005229 B822005294 B822005319 B822005288 B822005350 B822005377 B822005364 B822005349 B822005240 B822005347 B822005236 B822005234 B822005346 B822005238 B822005351 B822005365 B822005230 B822005315 B822005299 B822005374 B822005188 B822005293 B822005318 B822005256 B822005316 B822005327 B822005324 B822005329 B822005251 B822005257 B822005320		

	B822005321 B822005297 B822005200 B822005259 B822005170 B822005198 B822005331 B822005298 B822005199 B822005207 B822005317 B822005208 B822005206 B822005204 B822005220 B822005197 B822005203 B822005205 B822005185 B822005202 B822005330 B822005187 B822005268 B822005201 B822005322 B822005233 B822005246 B822005323 B822005333 B822005210 B822005196 B822005270 B823002108 B823002099 B823002098 B823002107 B823002103 B823002096 B823002101 B823002094 B823002092 B823002089 B823002100 B823002091 B823002106 B823002093 B823002097 B823002105		
召回原因简述	本产品在延续注册后，注册证号从国械注进20172202361变更为国械注进20172072361，印刷的产品标签上的注册证号存在错误（为旧注册证号），向客户主动召回该批次的产品。		
纠正行动简述（包括召回要求和处理方式等）	为客户更正错误的标签信息，替换设备标签		

报告单位：（盖章）

报 告 人：（签字）

负 责 人：（签字）

报告日期：2023年9月6日