令和 8 年 11 月 20 日作成

医療機器回収の概要
（クラス II）

1. 一般的名称及び販売名

一般的名称： 長時間心電用データレコーダ

販売名　　： 長時間心電図記録器　１１０ｅ

2. 対象ロット、数量及び出荷時期

品番　　：ECG-110E-01

製造番号　：14C001,14C002,14C003,14C004,14C005,14C006,14C007,14C008,14C009,14C010,
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出荷年月日　：令和 7 年 1 月 31 日～令和 8 年 2 月 27 日
出荷数量　　：890 台

3. 製造販売業者等名称
製造販売業者の名称　：　株式会社ジェイ・エム・エス
製造販売業者の所在地：　広島県広島市中区加古町１２番１７号
許可の種類　　：　第一種医療機器製造販売業
許可番号　　：　34B1X00001

4. 回収理由

14 日未満で記録が停止した場合は、医療従事者が記録確認をする時に明確にわかります。また、この場合も記録データ自体の信頼性に影響はありません。再測定を行う必要が生じる場合がありますが、本装置は重篤な病状ではない患者の日常生活下における心電図を記録収集して日内・日差変動を把握することを意図していることから、重篤な健康被害の発生はないものと考えます。なお、現在までに健康被害の報告はありません。

5. 危惧される具体的な健康被害

14 日未満で記録が停止した場合は、医療従事者が記録確認をする時に明確にわかります。また、この場合も記録データ自体の信頼性に影響はありません。再測定を行う必要が生じる場合がありますが、本装置は重篤な病状ではない患者の日常生活下における心電図を記録収集して日内・日差変動を把握することを意図していることから、健康被害の発生はないものと考えます。なお、現在までに健康被害の報告はありません。

6. 回収開始年月日

令和 8 年 11 月 20 日

7. 効能・効果又は用途等

本品は、医師の指導の下に患者が携行し、日常生活中の心電図を記録する装置である。

8. その他

9. 担当者及び連絡先

担当者　：　薬事・品質保証本部　後藤　誠
　　薬事・品質保証本部　高橋　義和
連絡先　：　株式会社ジェイ・エム・エス
　　広島県広島市中区加古町１２番１７号
電話番号：　082-243-6023
FAX 番号　：　082-243-5948

10. GTIN 及び該当ロット

[ヘッダー]GTIN(元梱),GTIN(販売),GTIN(個装／調剤),ロット番号,シリアル番号

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