DIVA Labs.

ECR (Engineering Change Request)

Proposed Change：	☑1. Design modification 設計修改 ☐2. Material change 材料變更 ☐3. Manufacturer change 製造商變更 ☐4. Factory change 工廠變更 ☐5. Process sequency change 工序變更 ☐6. Equipment / Tooling change 設備 / 模具變更 ☐7. Process / Method / Condition change 加工流程/方法 / 條件變更 ☐8.Add second source 新增替代料 ☐9. Others 其他：_____	**Initiator：** Kelly 0417 0930
Reason for Change：	客戶要求變更Carton label 以便和1A2A24235321600做區分	**EC No：** EC26040101
Model / Part No.：	1A2A24235321602 EPIQ-AUO, FRU	**Issue Date：** 2026/4/9 **Requester Dept.：** DV11S006
Implementation Type：	☑1. Immediately Change 立即切換 ☐2. Running Change 自然切換 ☐3. Other 其他：_____	**Customer Approval：** (confirmed by PM) ☐ Needed ☑ Not needed

Material Change Description（Please add pages as needed if the provided space is insufficient.）
物料變更說明（如不敷使用請逕行增頁）

No.	Subassembly		Part No.	Description	Q'ty	Location	Stock	Remark
1	1A2A24235321602	B	8MD539LB41A	CARTON LABEL (EPIQ-A,PHILIPS)	1			Change
		A	8MD539LB540	CARTON LABEL (EPIQ-AUO, FRU,PHILIPS)	1			
		B						
		A						
		B						
		A						

Comments 會簽意見

工單：1007700，1007750

R&D		Department 會簽部門								Approval
Initiator	Initiator's Direct Supervisor	DQE	PM	Sales	PE	PMC	SCM	PD	QA	R&D Director
Kelly 0409 1450	Michael 0410 1035 Leslie 0410 1030	[illegible] 0410 1020	Amber 0409 1735	Estela 0409 1750	Nick 0410 1340 [illegible] 0410 1140	Terry 0414 [illegible]	[illegible]	Bonen 0410 1600 Joanne 0410 1355	[illegible] 0414	Michael 0416 1730

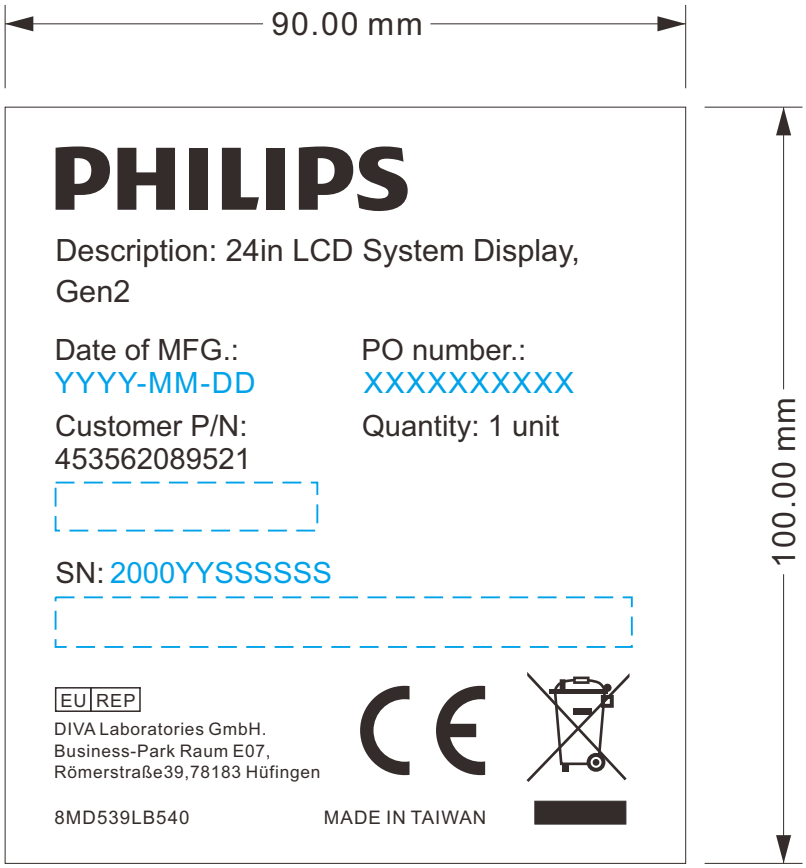
ECR (Engineering Change Request)

Engineering Change Assessment Item List 工程變更評估項目清單			
Document	Confirm	Authorized Dept.	Remark
1. Application for Revision of Specification or Drawing(s) for delivery 是否有修改交貨的規格或圖面	☑Yes ☐No need	RD	
2. Standards or Regulatories Impact 是否有評估適用之標準或主管機關之相關法規的申請	☐Yes ☑No need	DQE	無影响
3. Change point of PCB mounting PCBA插件位置是否變更	☐Yes ☑No need	RD	
4. PCBA Process Changes PCBA製程是否變更	☐Yes (Continue checking below) ☑No	PE	無影响
4-1) Change of Reflow temperature 迴焊溫度是否變更	☐Yes ☐No need		
4-2) Change of bonding temperature 膠合溫度是否變更	☐Yes ☐No need		
4-3) Change of Manual Soldering temperature 人工手焊工具之溫度是否變更	☐Yes ☐No need		
4-4) Change of storage condition after protection humidity package 防潮包裝完成後的儲存條件是否變更	☐Yes ☐No need		
5. Reliability test report (Test result and data) 是否有可靠性測試報告（測試結果及數據）	☐Yes ☑No need	DQE	無影响
6. Process FMEA（Medical only） 是否有進行製程失效模式與效應分析	☐Yes ☑No need	PE	無影响
7. Design FMEA （Medical only） 是否有進行設計失效模式與效應分析	☐Yes ☐No need	RD	
8. Risk Management（Medical only） 是否有進行風險管理評估	☐Yes ☑No need	RD	
9. Change points due to the modification 是否此修改會延伸導致其他變更點	☐Yes ☑No need	RD	

ECR (Engineering Change Request)

4-1) Change of Reflow temperature 迴焊溫度是否變更	☐Yes ☐No need	PE	
4-2) Change of bonding temperature 膠合溫度是否變更	☐Yes ☐No need		
10. Initial Supply Control implements plan or result. 是否有實施供料控制評估	☐Yes ☐No need		
10-1) Confirm the work order or order number or date for the implementation start of the engineering change. 確認工程變更開始實施之工單或訂單號碼或日期。	☑Yes ☐No need	PMC	工單：1007700 2026.07.22 1007750 2026.08.26
10-2) Coordinate the handling methods for related products and materials. 協調相關產品及材料處理方法。	☑Yes ☐No need		
10-3) Arrange the production schedule. 處理生產日程之安排。	☑Yes ☐No need		
10-4) Control the changed materials. 變更材料之管制。	☐Yes ☑No need		
10-5) Establish relevant execution control records for EC materials, register traceability data for each material. 建立有關工程變更物料之相關執行管控記錄、登錄各項物料追溯性資料。	☑Yes ☐No need		
11. Training Requirement 若此一變更影響製程或檢驗，是否需要再做人員訓練	☐Yes ☑No need	PE	無影响
12-1. Modification contents (For example, the following documents) 是否有評估此變更之各項相關文件（如下） ☐ QC control plan ☐ Service Manual ☐ Others	☐Yes ☑No need	QA	無影響
12-2. Modification contents (For example, the following documents) 是否有評估此變更之各項相關文件（如下） ☐ SIP ☑ SOP ☐ Others	☑Yes ☐No need	PE	
12-3. Modification contents (For example, the following documents) 是否有評估此變更之各項相關文件（如下） ☑ MDF ☑ DMR ☐ Approval Sheet ☐ Engineering Spec ☐ Others	☑Yes ☐No need	RD / DQE	

REV.	DATE	DESCRIPTION	BY	APVD



Note:

1.Use 3MDL4XLB440 Blank label.

2.Use Ricoh #B110A ribbon.

3.PO number.:Please follow each purchase order number

4.Customer P/N掃出後的條碼為453562089521

5.Serial Number 12 digital Rule:

Production :

2 0 0 0 2 2 0 0 0 0 0 1

量產品		年分		流水號
Production		MFG.Year		Serial No.

PM / SALES		THIRD ANGLE PROJECTION	UNITS: mm	SCALE: 1/1	SHEET: 1/1	MODEL NO.: EPIQ-AUO, FRU
Amber 0401 1830			MATERIAL: SEE NOTES		TREATMENT: SEE NOTES	
PE	PCD	DSGD by Killy	2026/01/09	PART NAME: CARTON LABEL		
John 0402 0930	Joanne 0408 2050	APVD by		PART NO.:8MD539LB540		VER.0
		APVD NO.:	FILE NAME: EPIQ-AUO, FRU.cdr	DIVA Laboratories,Ltd.		

Killy_Lee

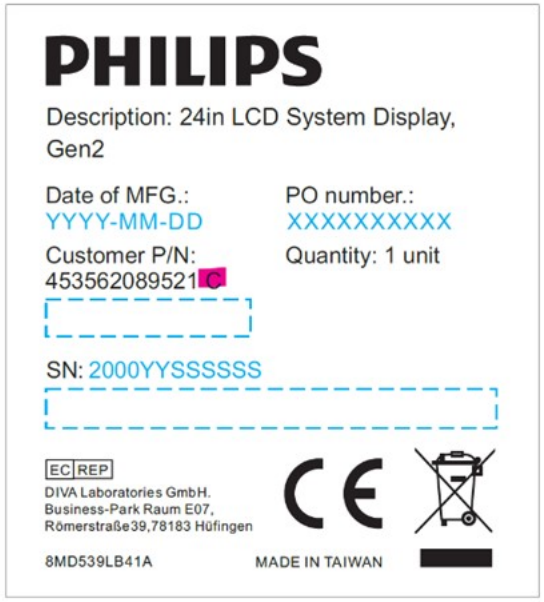
寄件者: Amber_Tsao <amber_tsao@diva.com.tw>
寄件日期: 2026年1月9日星期五 下午 4:44
收件者: 'Killy_Lee'
副本: Nick_Lin 林益銓; JoanneHuang 黃瓊玉; 'ryan_wang'; 'Hu, Estela (Partner)'
主旨: RE: MoM_Ultrasound global service parts (FRU) direct buy -DIVA

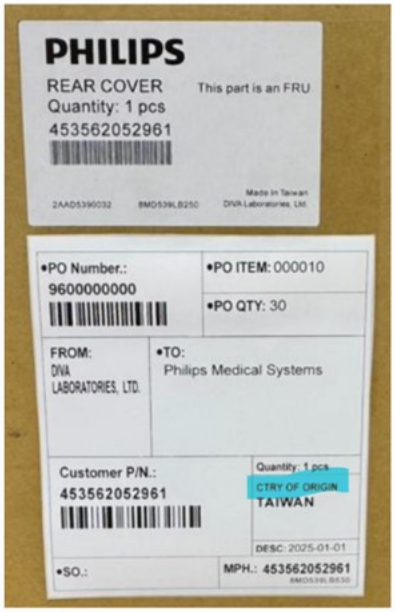
Hi Killy,

針對label，客戶有以下額外的2點要求，再請協助更新下圖面給我，感謝!

1. 1A2A24235321602，EPIQ-AUO, FRU的Carton label_8MD539LB41A的Philips 12NC後面的「C」請協助拿掉
   因為8MD539LB41A是與1A2A24235321600共用，所以理應需要一個新的carton label PN for 1A2A24235321602
   沒有要去動到正常出貨版本的label

2. 3項FRU的shipping label，8MD539LB500、8MD539LB530、8MD539LB520上的「CTRY OF ORIGINAL」請改成「MADE IN」

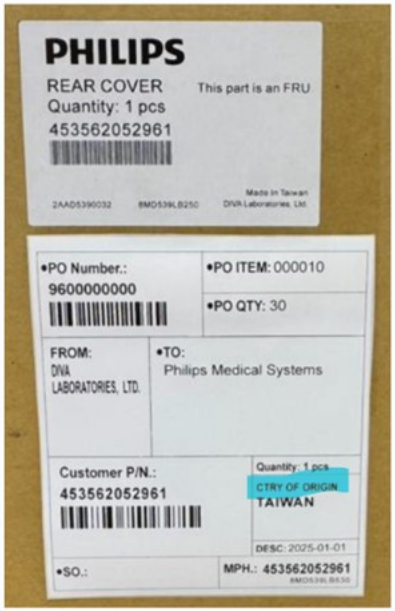




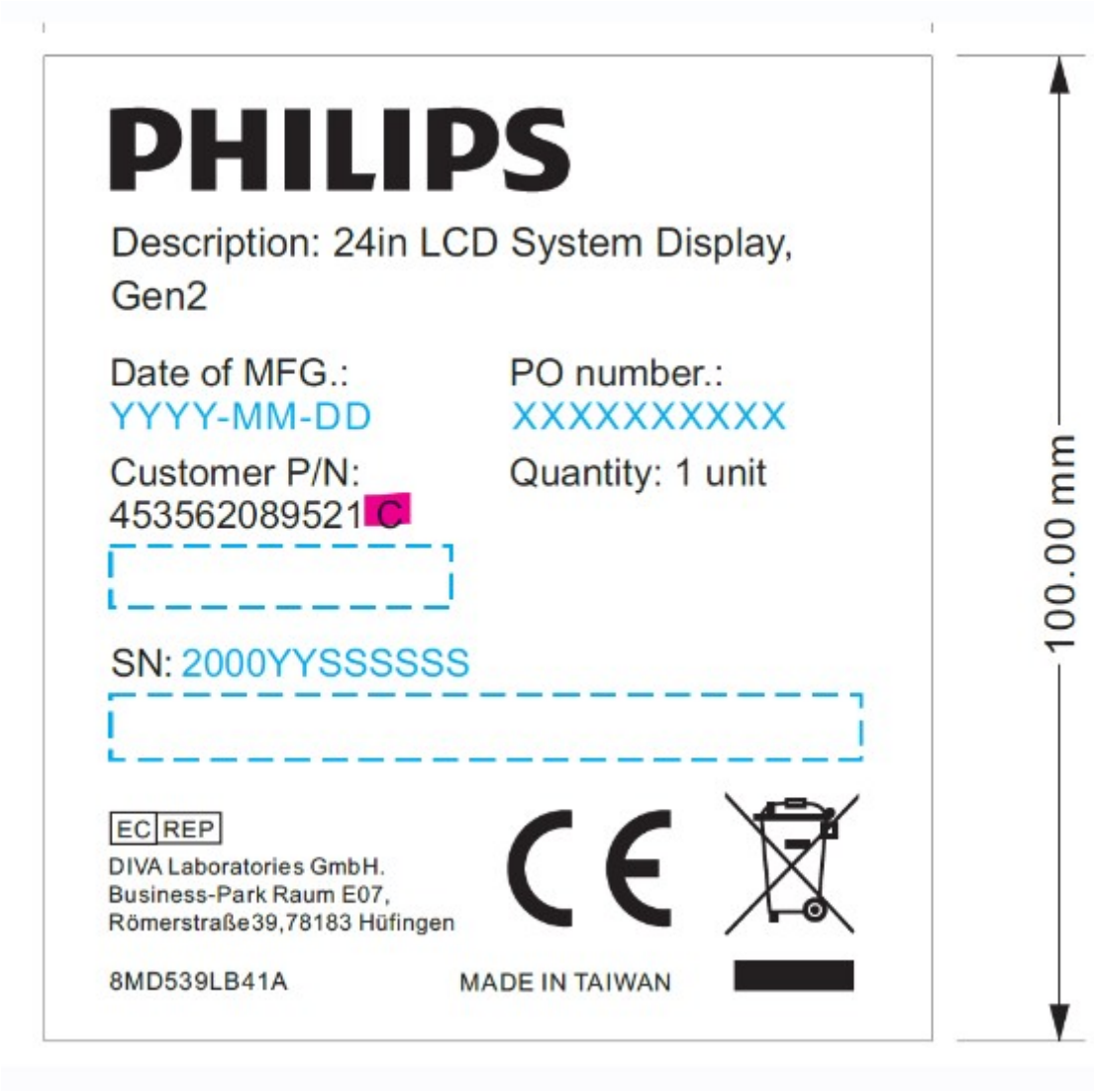
Best regards,
Amber Tsao

From: BAI, Felix <felix.bai@philips.com>
Sent: Friday, January 9, 2026 3:43 PM
To: amber_tsao <amber_tsao@diva.com.tw>
Cc: YANG, Jimmy <jimmy.yang@philips.com>; QIAN, Chen Ming <ChenMing.QIAN@philips.com>; More, Sagar <Sagar.More@philips.com>; Hu, Estela (Partner) <estela_hu@diva.com.tw>; 'ryan_wang' <ryan_wang@diva.com.tw>; Tsai, Una (Partner) <UNA_TSAI@DIVA.COM.TW>
Subject: RE: MoM_Ultrasound global service parts (FRU) direct buy -DIVA

HI Amber：
Thank you very much for your update.
Yes , your action is acceptable.
Here still 2 tiny correction need your action per Philips SPS requirements.
The 3 components' shipping label:
"CTRY OF ORIGINAL" change to "MADE IN"



453562089521 box label do not include Revision letters, the letter C



Felix BAI

Senior Supplier Process Engineer - STET
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E-mail: felix.bai@Philips.com
Address: No.258 Zhongyuan Road,Suzhou Industrial Park, China, 215024

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innovation + you

From: Amber_Tsao <amber_tsao@diva.com.tw>
Sent: Friday, January 9, 2026 2:52 PM
To: BAI, Felix <felix.bai@philips.com>
Cc: YANG, Jimmy <jimmy.yang@philips.com>; QIAN, Chen Ming <ChenMing.QIAN@philips.com>; More, Sagar <Sagar.More@philips.com>; Hu, Estela (Partner) <estela_hu@diva.com.tw>; 'ryan_wang' <ryan_wang@diva.com.tw>; Tsai, Una (Partner) <UNA_TSAI@DIVA.COM.TW>
Subject: RE: MoM_Ultrasound global service parts (FRU) direct buy -DIVA

Caution: This e-mail originated from outside of Philips, be careful for phishing.

Hi Felix,

Please see our reply in blue as below. Thank you.

First , The barcode should not include the Rev information, I marked with red background.
If **Rev: D** in the 12NC Barcode , SPS can not scan it . you can give a separate barcode for Revision .
You need to update the label barcode and offer clear instructions to avoid mistakes in future operations.





Diva: Actually the label barcode information only includes 12NC 453562075531, please refer to the attached photo '453562075531 barcode scan'.
To avoid SPS confusion, we removed the Rev information from the box label and shipping label. Please see the attached updated label drawing.
We also update the related documents as attached, these documents all uploaded to following share folder link.

https://divalabsnas.myqnapcloud.com/share.cgi?ssid=4848e6e9e9d740e18938b39c1231d7b6

Second, the badge is buckle package ,
Affix a **highly visible label** to inform SPS that the carton contains **multiple components**,
with reference to the following details, you can choose 1 method to remind SPS .
Give me your update evidence (update related output files)





Diva: We updated the box label drawing as attached to add the words 'BULK 30'.
We also updated the related documents as attached, these documents all uploaded to the share folder.

Third. Pls check your barcode is quality and check it is readable by the scanner.
Diva: Please see attached photo 'barcode info by scanner', the scanner can correctly read all information.

Best regards,
Amber Tsao

DIVA Laboratories, Ltd. | Product Management Dep.
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F:+886-2-2226-2423 | W: www.diva.com.tw
9F., No.351, Sec. 2, Zhongshan Road, Zhonghe District , New Taipei City 235602, Taiwan R.O.C.

From: BAI, Felix <felix.bai@philips.com>
Sent: Wednesday, January 7, 2026 4:04 PM
To: amber_tsao <amber_tsao@diva.com.tw>

Cc: YANG, Jimmy <jimmy.yang@philips.com>; QIAN, Chen Ming <ChenMing.QIAN@philips.com>; Hu, Estela (Partner) <estela_hu@diva.com.tw>; 'ryan_wang' <ryan_wang@diva.com.tw>; Tsai, Una (Partner) <UNA_TSAI@DIVA.COM.TW>; More, Sagar <Sagar.More@philips.com>
Subject: RE: MoM_Ultrasound global service parts (FRU) direct buy -DIVA

HI Amber:

After reviewing your deliverables and checked by Philips SPS team.

Something needs your improvement.

First , The barcode should not include the Rev information, I marked with red background.

If **Rev: D** in the 12NC Barcode , SPS can not scan it . you can give a separate barcode for Revision .

You need to update the label barcode and offer clear instructions to avoid mistakes in future operations.





Second, the badge is buckle package ,

Affix a **highly visible label** to inform SPS that the carton contains **multiple components**,

with reference to the following details, you can choose 1 method to remind SPS .

Give me your update evidence (update related output files)

設計變更審查會議記錄

時間	20260409	地點	801	主席	Amber
參與人員	Tony、Amber、Killy、世炫				

討論與決議事項：

*客戶要求不共用，所以 Carton label 重新申請料號

DIVA 料號	Philips 12NC	客戶型號	Label	新料號	備註
1A2A24235321602	453562089521	EPIQ-AUO, FRU	Carton label	8MD539LB540	客戶要求不共用需申請新料號

變更號碼：EC

變更機種名稱 ：1A2A24235321602 PIQ-AUO, FRU

設計變更原因 ： 客戶要求變更

設計變更描述 ： Carton label 內容料號變更

導入時程 ： Normal

客戶審查 ： Not Need

一. 研發課評估 ：

單位	審查內容	附加文件
EE :	經評估變更與軟體設計無關,不會造成軟體安全性影響	無
FW :	經評估變更與軟體設計無關,不會造成軟體安全性影響	無
ME :	經評估變更與軟體設計無關,不會造成軟體安全性影響	無
SW :	經評估變更與軟體設計無關,不會造成軟體安全性影響	無
DQE :	經評估變更與軟體設計無關,不會造成軟體安全性影響	無

二. 結論 ：

1.LABELS UPDATE.

2.開發單位各部門評估後,此設計變更不會對產品預期用途造成影響,

功能	設計變更內容無關功能影響
性能	設計變更內容, 無關產品性能影響
可用性	無影響, 沒有使用上的風險
安全性	組裝方式沒有改變， 沒有安全性風險,
法規	經審查, 沒有影響法規內容

人員簽到：