檔　　號：
保存年限：

立恩威國際驗證股份有限公司　函

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發文日期：中華民國 106 年 7 月 4 日
發文字號：立恩威驗展字第 2017070401 號
速別：普通件
密等及解密條件或保密期限：普通
附件：如文

台灣醫療暨生技器材工業同業公會
收 106. 07. 05 文
檔號: 106482

主旨：DNV GL NB 0434 變更為 DNV GL NEMKO PRESAFE NB 2460 轉換說明

說明：

一、 Det Norske Veritas(簡稱 DNV)成立於 1864 年，總部位在挪威首都奧斯陸，為一個專業、獨立、自主的非營利機構，以『保護生命、財產與環境』為宗旨; 台灣分公司_ 立恩威國際驗證股份有限公司 (DNV GL Business Assurance) 成立於 1992 年，現分別於台北及高雄設立分公司及辦事處，目前全職員工中 70%為技術人員，碩博士佔 85%; 自 1996 年開始，DNV GL Business Assurance 即為符合歐盟醫療器材指令(Medical Device Directive)的認可驗證機構 (Notify Body)，為國內的醫療器材廠商提供 ISO 13485 與 CE Marking 技術支援與本土化的驗證服務; DNV 與德國 GL 於 2013 年正式合併為

DNV GL 集團，DNV GL 集團亦位居全球三大管理系統驗證機構之列。

二、 DNV GL Nemko Presafe AS 成立於 2012 年，是由 DNV GL 和 Nemko 合資創建的醫療器材驗證服務機構; 自 2012 年以來，分別通過合資雙方 DNV GL BA(NB0434) 與 Nemko AS(NB 0470) 提供驗證服務。建立合資企業的初衷是合併雙方的醫療器材驗證部門，將現有雙方業務整合到單一合法驗證主體; 鑒於目前業務整合已經完成，同時考慮針對所有醫療器材驗證機構授權的強制更新要求，我們將獲得授權的相關驗證業務統一歸入 DNV GL Nemko Presafe AS_ 驗證機構編號 2460。

三、 DNV GL Nemko Presafe AS 仍保持由 DNV GL Business Assurance AS 與 Nemko AS 共同所有，法律主體合併過程不影響人員、操作流程以及證書有效性; 從 2017 年 3 月 1 日起，所有新發證書及現有有效證書都將轉到新的驗證機構，即 DNV GL Nemko Presafe AS (NB2460) 。

四、 立恩威國際驗證股份有限公司於 2017 年 3 月 9 日發出 Notification Body 變更通知預告予醫療器材驗證客戶，2017 年 3 月 10 日發出 Notification Body 變更正式通知予醫療器材驗證客戶，2017 年 3 月 20 日至 2017 年 3 月 24 日發出 MDD 驗證機構轉換合

約予醫療器材驗證客戶，另外針對轉換過程中其主要的相關事項亦整理條列「醫療器材驗證機構變更 FAQ」予醫療器材驗證客戶。

五、　隨函檢附「醫療器材驗證機構變更告知函」、「醫療器材驗證機構變更時間表」及「醫療器材驗證機構變更 FAQ-v2」。

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NOTICE ON TRANSITION OF NOTIFIED BODY FROM DNV GL -BUSINESS ASSURANCE NB0434 TO DNV GL NEMKO PRESAFE NB2460

Dear Valued Customer,

DNV GL Nemko Presafe AS has, since its foundation in 2012, been a joint venture company owned by DNV GL and Nemko to provide services in the field of medical device certification. Since 2012 certification has been delivered under the notifications of both owners, DNV GL - Business Assurance (NB 0434) and Nemko AS (NB 0470).

The founding principle of the joint venture was to completely merge the medical device departments, transitioning existing owner notifications to a single new legal and regulatory entity. As part of the completion of the merger process and in conjunction with the mandatory renewal of designation for all Medical Devices Directive Notified Bodies, we have now unified our notification to DNV GL Nemko Presafe AS, Notified Body number 2460.

We received confirmation from the Norwegian national authorities on 17th January 2017 of the completion of the notification process for DNV GL Nemko Presafe AS for Medical Device Directive and the NANDO database has been updated on 14th February reflecting the notification.

On 18th May 2017 DNV GL Business Assurance Norway AS (NoBo 0434) and 18th April 2017 Nemko AS (NoBo 0470) will cease to be notified bodies for Medical Devices Directive. Together with this letter we enclose a regulatory agreement to confirm contractual relations with DNV GL Nemko Presafe AS. We kindly ask you to complete this agreement as soon as possible and before 18th May 2017.

From 1st March 2017, all new certificates and re-certifications will be issued by NoBo 2460. We are also obliged to initiate a transfer process of all current valid certificates issued under legacy designations to the newly notified DNV GL Nemko Presafe AS 2460, which must be completed within six months from the date contract is signed with DNV GL Nemko Presafe AS and latest by 17th November 2017.

We confirm that all products which are manufactured within six months from the date the agreement with DNV GL Nemko Presafe AS is completed remain correctly certified and may continue to bare the legacy notified body numbers and marking.

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We do understand that there may also be special circumstances in which such a limited timeframe might be problematic. We will make every effort to support manufacturers and we will not re-evaluate compliance or implement new conditions or technical requirements as part of the transfer.

We would like to ask you for your understanding and to communicate to your respective local DNV GL office any underlying conditions that you consider might become an unavoidable obstacle in the process of timely transferring of certificates to legal entity DNV GL Nemko Presafe AS and changing the Notified Body number on your devices, labels, packaging, instructions for use etc.

This will allow us time to evaluate the circumstances and properly plan and help with communication with National Competent Authorities to find the most suitable solution.

Anticipating your practical questions, we would like to confirm:

- There will be no changes to the established operational routines.
- There will be no changes in the DNV GL Business Assurance AS or DNV GL Nemko Presafe AS structure or personnel
- Continuity of current certificate validity dates will be preserved.
- The schedule of your periodic audits and scheduling practice will not change.
- A new regulatory agreement will be required between you, as a manufacturer, DNV GL Business Assurance local units, and DNV GL Nemko Presafe AS. These agreements will be sent to you on or shortly after 1st March 2017.
- We would like to reassure manufacturers with valid certificates that the only changes we foresee to transfer their CE certification to DNV GL Nemko Presafe AS is to complete new regulatory agreements, to update the notified body number where it appears in their products and technical documentation and register new certificates with national authorities in countries of distribution, if required.

We strongly believe that a common quality management system and consolidated resources within one Notified Body will help us to improve the quality of services we provide.

We would like to thank you for patience and cooperation in this transitional period.

Yours sincerely,

Luca Crisciotti		
For DNV GL Business Assurance AS	For DNV GL Nemko Presafe AS	For DNV GL Nemko Presafe AS
Chief Executive Officer Luca Crisciotti	Managing Director Kjetil Olav Flaatedal	Certification Manager- MDD Alexey Shiryaev

MEDICAL DEVICE DIRECTIVE – NOTIFIED BODY TRANSFER MILESTONES

DNV GL Nemko Presafe AS (Notified Body 2460)

In 2011 DNV GL and Nemko entered a joint venture forming DNV GL Nemko Presafe AS to merge their Medical Device and Hazardous Area certification businesses with the intention of operating as a single legal and regulatory entity.

DNV GL Nemko Presafe AS remains jointly owned by DNV GL Business Assurance AS and Nemko AS.

The personnel, operational routines and certificate validity are not affected by the finalisation of the merger of the legacy operations. From March 1st 2017, all new and current valid certifications will be transferred to the newly notified entity, DNV GL Nemko Presafe AS.

JANUARY 18/01

DNV GL Nemko Presafe AS (NoBo 2460) is notified by Norwegian authorities for Council Directive 93/42/EEC (Medical Devices Directive).

MARCH 01/03

All new MDD certificates will be issued by DNV GL Nemko Presafe AS (NoBo 2460).

MARCH 01/03

New regulatory agreements for transition of existing valid certificates to the new notified body entity will be circulated to customers. No significant changes to existing practice are anticipated - this is required purely for regulatory purposes between the legal manufacturer and the new DNV GL Nemko Presafe AS notified body legal entity.

APRIL 17/04

Nemko AS (NoBo 0470) ceases to be notified for Directive 93/42/EEC.

MAY 17/05

DNV GL - Business Assurance (NoBo 0434) ceases to be notified for Directive 93/42/EEC.

MAY 18/05

The last date on which new regulatory agreements, distributed on 1st March must be completed to maintain certificate validity. The date of signing starts a 6-month transfer process.

NOVEMBER 17/11

The last possible date for completion of the 6-month transition period for legacy certificate holders. (Note that this date could be earlier, depending on when you sign the new regulatory agreement).

Nemko DNV·GL

Presafe
A DNV & NEMKO COMPANY

DNV GL Nemko Presafe is a joint venture company wholly owned by DNV GL and Nemko.

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醫療器材驗證機構變更 FAQ - Ver. 2　Date:2017.6.29

[新驗證機構證號 NB2460 議題區]

No.	議題	回覆
1	**轉換為 2460 需要再進行稽核嗎?**	**不需要。**
2	轉換為 2460 需要再支付額外費用嗎?	不需要。
3	**新的 2460 證書還沒下來前，原有的 0434 還可以用嗎?**	**原 0434 證書將於 2017 年 05 月 17 日失效，但 0434 產品只要在 2017 年 11 月 17 日前清關(進入歐盟)的產品均可銷售。**
4	什麼時候可以開始使用 2460?	收到新證書之後才能開始銷售標示 2460 的產品。
5	**轉換需要提供哪些文件才能轉換?**	**需要轉換合約, DOC, 更新後的 2460 標籤, 更新後的 2460 使用說明書。**
6	何時需要通知歐體代表，轉換 Notified Body?	收到新證書之後，再通知。
7	**何時需要通知代理商/ 進口商 (歐洲以外的國家)，轉換 Notified Body?**	**收到新證書之後，再通知。**
8	2460 是否已在歐盟網站公告？歐盟是否有轉換程序?	NB2460 已於 3/1 發佈，如下所示 http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.notifiedbody&refe_cd=NANDO%5FINPUT%5F215008 轉換程序根據文件 BOG_BPG_2006-1-Change of Notified Body http://www.doks.nbog.eu/Doks/NBOG_BPG_2006_1.pdf
9	**OBL 由 0434 轉 2460 時，OBL 原品牌廠的 CE 證書是否有效？**	**收到新證書之後，再通知原品牌廠，原品牌廠再向本身的 Notified Body 備案，CE 證書仍有效。**

[原驗證機構證號 NB0434 議題區]

No.	議題	回覆
1	**已經生產的 0434 產品，要如何處理? 可以繼續出貨多久?**	**只要在 2017 年 11 月 17 日前清關(進入歐盟)的產品均可銷售。**
2	已經於歐盟市場上販售、流通標示 0434 的產品要如何處理?	不需回收，可持續銷售。
3	**0434 的庫存太多，如果超過 2017 年 11 月 17 日前的緩衝期尚未清關該怎麼辦?**	**依據規定，製造商可請其歐體代表或代理商向當地衛生主管機關申請 0434 效期展延，DNV GL 可依照需求提供證明函或聲明書等相關協助。**
4	轉換期間，申請 CE 新案或修改證書是否直接發 2460 證書?	是的，直接發 2460 證書。
5	**轉換期間，如已完成稽核，但證書還沒發證，是否改發 2460 證書?**	**是的，直接發 2460 證書。**
6	如果不轉換為 2460，0434 產品是否可持續銷售?	只要在 2017 年 11 月 17 日前清關(進入歐盟)的產品均可銷售，未清關的產品必須改標新的 2460 否則不得銷售。
7	**是否能直接標示 2460 銷售?**	**需等到收到更新之證書後才能開始銷售標示 2460 的產品，發送更新證書的時間將以轉換合約中，製造商所填寫預期開始使用 2460 的日期為基準。**
8	如果有其他特殊的考量，如何與 DNV GL 連繫?	請致電以下人員，我們會安排專人拜訪 (02)8253 7800 分機 124 林秀敏 (02)8253 7800 分機 134 李科樺