DNV GL醫療器材驗證服務現況說明

TMBIA拜訪簡報

25 January 2018

NB轉換說明

緣由

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。現在，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。

流程

JANUARY 18/01

2017-01-18 起，挪威國家主管機關批准 DNV GL Nemko Presafe AS 為醫療器材指令的驗證機構 (公告號為 2460) 。

MARCH 01/03

2017-03-01 起，所有的醫療器材證書都由 DNV GL Nemko Presafe AS 簽發。

MARCH 01/03

2017-03-01 起， 新的協定將和客戶簽訂，它是有關於現存有效的證書過渡到新的驗證機構的事宜。 該過渡針對於現行的流程沒有大的變化。 主要目的是為了滿足製造商和新的驗證機構 DNV GL Nemko Presafe AS 的一些法規要求。

APRIL 17/04

2017-04-17 日起，Nemko AS 的公告號（0470）將退出醫療器材指令的驗證。

MAY 17/05

2017-05-17 日起，DNV GL - Business Assurance 的公告號（0434）將退出醫療器材指令的驗證。

MAY 18/05

2017-05-18 日起，它是與客戶 2017-03-01 開始簽訂新的協議的截止日期， 所有客戶在這之前必須簽訂協定， 以保持證書的持續有效性。 從簽字日開始， 將開始 6 個月的證書過渡轉換期。

NOVEMBER 17/11

2017-05-18 至 2017-11-17， 6 個月的轉換過渡期結束（2017-11-17 是最後一天， 但是可能會更早， 這個取決客戶簽訂協定的時間）。

備註: 2017 年 11 月 17 日是產品最終進入歐盟的入關日期限。

進度

- **2017.3.10**

發出Notification Body變更正式通知予醫療器材驗證客戶

- **2017.3.20~2017.3.24**

發出MDD驗證機構轉換合約予醫療器材驗證客戶

- **2017.3.27~2017.5.17**

回收醫療器材驗證客戶MDD驗證機構轉換合約

進度

- **2017.6.29**

DNV GL應洪盛隆理事長之邀，至公會與會員廠說明NB0434轉NB2460事宜，會中呈上報告書一份及會後提供說明函及正式公文上傳於公會官網
http://www.tmbia.org.tw/big5/news_1.php?id=10600253

- **2017.5.17~2017.11.17**

進行醫療器材驗證客戶證書轉換程序

- **所有客戶已於2017.11.17轉換完成並開始使用新證書**

產品標示轉換

- 收到 NB 2460 證書時 (發證日後) 就不可以在生產貼標 0434, 但是之前 生產貼標 0434 的產品可繼續出貨分銷到 (發證日加 6 個月)

- 如 NB 2460發證日 2017-05-17, 那麼 2017-05-17 後就不可以生產貼標 0434, 必須生產貼標 2460, 但是於 2017-05-17 前生產貼標 0434 的產品仍可出貨一直到 2017-11-17

- 如 NB 2460發證日 2017-08-01, 那麼 2017-08-01 後就不可以生產貼標 0434, 必須生產貼標 2460, 但是於 2017-08-01 前生產貼標 0434 的產品仍可出貨一直到 2018-02-01

- 如 NB 2460發證日 2017-11-17, 那麼 2017-11-17 後就不可以生產貼標 0434, 必須生產貼標 2460, 但是於 2017-11-17 前生產貼標 0434 的產品仍可出貨一直到 2018-05-17

- 如果按以上的規定還有 0434 庫存 建議的商業操作模式 可選擇 非歐盟,非等同採認CE證書的國家 (如 內銷, 大陸, 韓國, 日本, 美國....) 來消耗庫存

"I can confirm that your interpretation is correct. You may manufacture the products with the old NB 0434 number until the date you receive your new Presafe NB 2460 certificate. You may then distribute the products bearing the legacy number NB 0434 for another 6 months. I.e. if your Presafe NB 2460 certificate is issued on 17th November, you can distribute the products with the old legacy number NB 0434 until 17th May 2018 when Presafe certificate is issued on 17th November 2017. But production with 0434 must stop before 17th November 2017.
"

公告

DNV GL Nemko Presafe AS
P.O Box 116, 1300 Sandvika
Telephone: +47 67 57 88 00
www.presafe.com

重要訊息:

DNV GL 係為醫療器材指令 (93/42 / EEC) 的公告機構和醫療器材品質管理系統 (ISO 13485) 的驗證機構，近期我們得知台灣業界，正流傳對於 DNV GL 狀態有疑慮的訊息。

這些訊息並不能準確反映出目前 DNV GL 公告或認證的狀態，這種方式已經誤導市場去理解我們的驗證有效性，和 DNV GL 作為醫療器材驗證服務提供者的角色。

2011 年，DNV GL 和 Nemko，兩者係為挪威的公告機構與已認證的驗證機構，成立了合資公司 DNV GL Nemko Presafe（Presafe），旨在合併其醫療器材認證活動在單一的法律和監管機構。2017 年，這個合併過程已經完成將所有目前合作夥伴的有效證書，轉換監管責任到新的公告機構實體，Presafe，號碼 2460。

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

無論公告機構或當地單位合作組織，其人員，能力或運作事務沒有任何變更。

為了避免諸多不必要的疑問與猜測，我們在此確認 DNV GL 當地辦事處的代表性，保有全面授權以簽署合約，並代表公告機構 Presafe 進行所有相關活動。

Trond Lund
Chief Executive Officer
DNV GL Nemko Presafe

Otto Hughes
Global Product Assurance Manager
DNV GL Business Assurance

DNV GL Nemko Presafe AS
P.O Box 116, 1300 Sandvika
Telephone: +47 67 57 88 00
www.presafe.com

Important Information:

We are aware of recent information released to the market in Taiwan concerning the status of DNV GL as a Notified Body for Directive 93/42/EEC (Medical Devices Directive) and as a Certification Body for ISO 13485 (Medical Devices – Quality Management Systems.)

The information does not accurately reflect the status of the notification or accreditations belonging to DNV GL and has been presented in such a way to mislead the market regarding the validity of our certification and role of DNV GL as a provider of Medical Device certification services.

In 2011, DNV GL and Nemko, both notified bodies and accredited certification bodies based in Norway, formed a joint-venture company, DNV GL Nemko Presafe (Presafe) with the aim to merge their Medical Device certification activities in a single legal and regulatory entity. This process was completed in 2017 with a managed transition of regulatory responsibility for all current valid certificates of the legacy partners to the new Notified Body entity, Presafe, number 2460.

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

There is no change in the personnel, competence or operating routines in either the Notified Body or the local unit partner organizations.

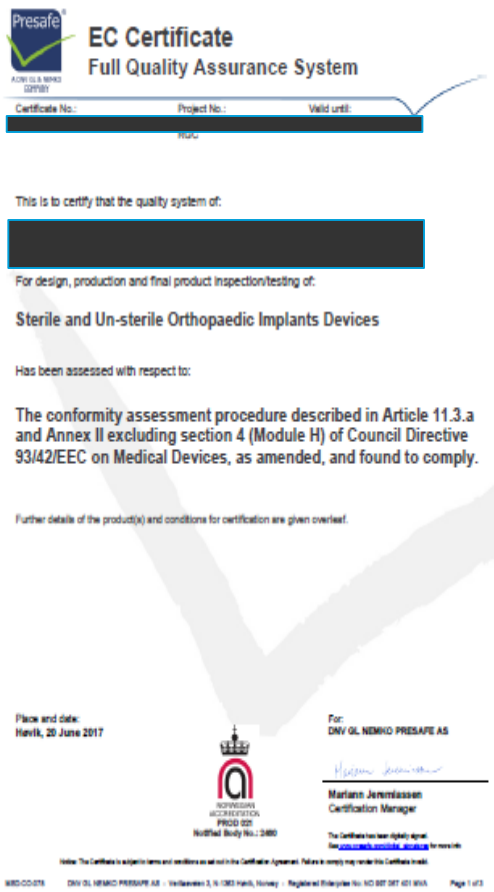
For the avoidance of doubt, we confirm that representatives from local offices of DNV GL remain fully authorized to enter in to contracts and perform all relevant activities on behalf of the Notified Body, Presafe.

Høvik, Norway
17th November 2017

Trond Lund
Chief Executive Officer
DNV GL Nemko Presafe

Otto Hughes
Global Product Assurance Manager
DNV GL Business Assurance

NB 2460 證書



EC Certificate
Full Quality Assurance System

Certificate No.: [redacted] Project No.: Valid until:

This is to certify that the quality system of:

[redacted]

For design, production and final product inspection/testing of:

Sterile and Un-sterile Orthopaedic Implants Devices

Has been assessed with respect to:

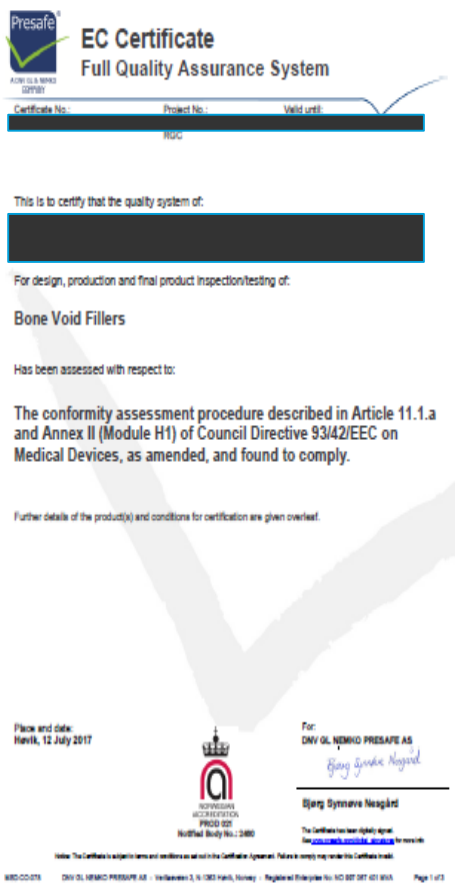
The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 June 2017

For:
DNV GL NEMKO PRESAFE AS

Marianne Jenmlassen
Certification Manager



EC Certificate
Full Quality Assurance System

Certificate No.: [redacted] Project No.: Valid until:

This is to certify that the quality system of:

[redacted]

For design, production and final product inspection/testing of:

Bone Void Fillers

Has been assessed with respect to:

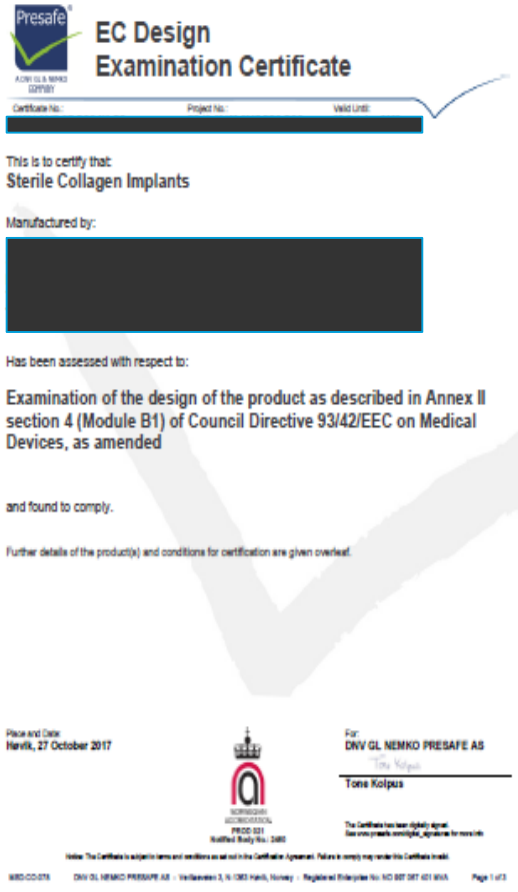
The conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 July 2017

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård



EC Design
Examination Certificate

Certificate No.: [redacted] Project No.: Valid Until:

This is to certify that:
Sterile Collagen Implants

Manufactured by:

[redacted]

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 (Module B1) of Council Directive 93/42/EEC on Medical Devices, as amended

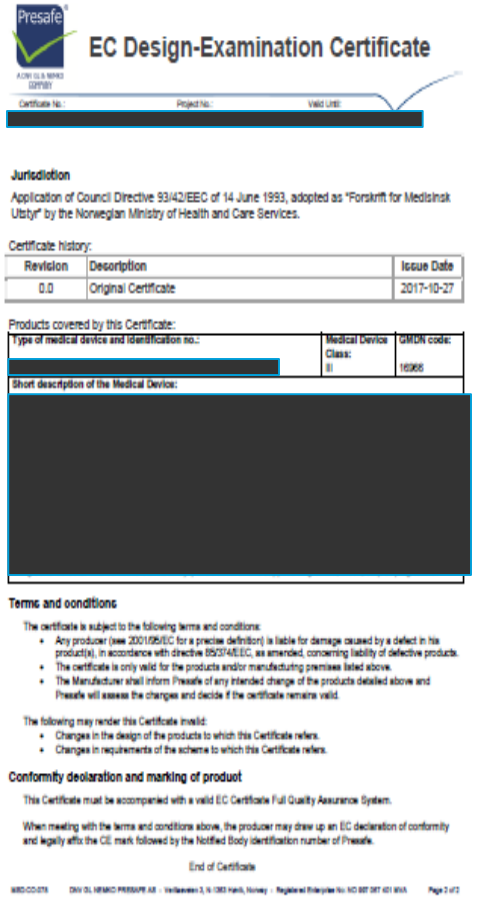
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 27 October 2017

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus



EC Design-Examination Certificate

Certificate No.: [redacted] Project No.: Valid Until:

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-10-27

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
[redacted]	III	16966

Short description of the Medical Device:

[redacted]

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

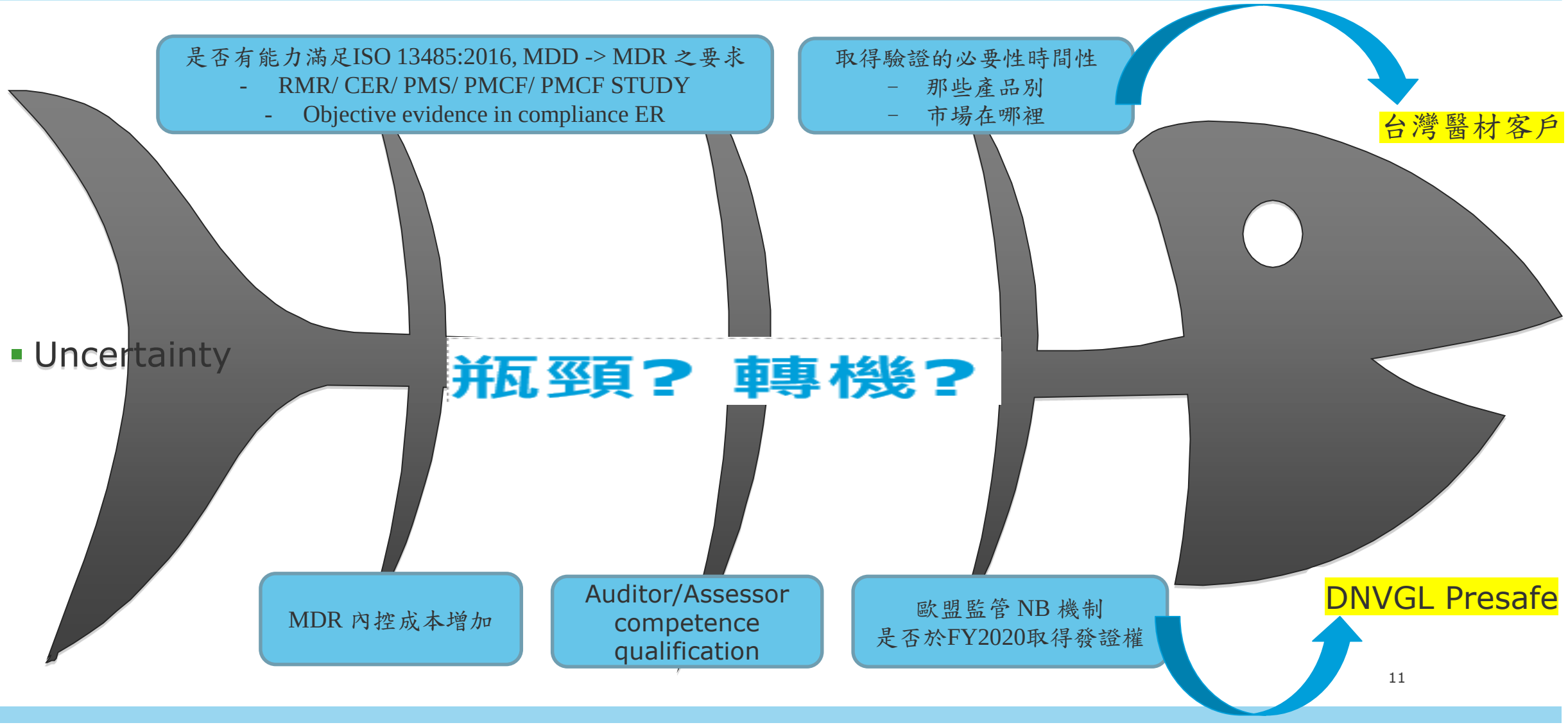
This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

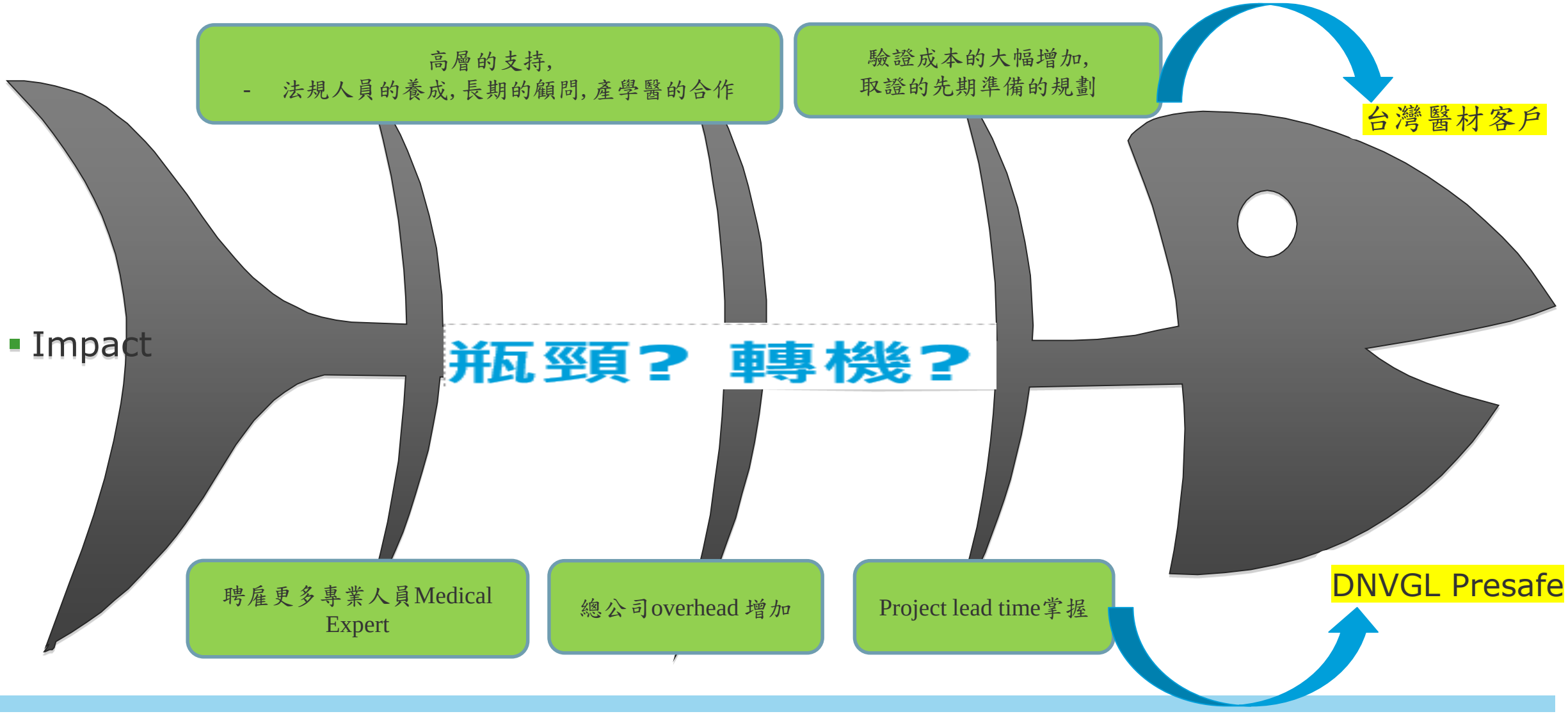
不確定性與衝擊性

DNVGL Presafe vs Medical Manufacturer



DNVGL Presafe vs Medical Manufacturer

- Impact



結語

真心感謝，醫客為尊

二十年來的耕耘，陪伴三百多家醫療器材客戶一起成長.....

一路走來，三心為本（讓心，掛心，真心）始終如一.....

我們已經盡力，但是還不夠努力；已經盡職，但是付出還不夠.....

懇請給彼此多些時間和空間，相信明天會更好.....