



DNV·GL

DNV GL BUSINESS ASSURANCE
NORWAY AS

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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.

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,



For DNV GL Business Assurance AS

Chief Executive Officer
Luca Crisciotti



For DNV GL Nemko Presafe AS

Managing Director
Kjetil Olav Flaatedal



For DNV GL Nemko Presafe AS

Certification Manager- MDD
Alexey Shiryaev