QNET LLC

CE Marking Medical Devices and Machinery Authorized Representative

May 9, 2013

Mr. Douglas Bell
Chair, Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Comments on the Transatlantic Trade and Investment Partnership

Dear Mr. Bell:

In response to the April 1, 2013 Federal Register Notice (78 Fed. Reg. 19566), QNET LLC submits the following comments in support of the negotiation of a Transatlantic Trade and Investment Partnership (TTIP) agreement with the European Union (EU).

Introduction

QNET LLC is consulting firm that specializes in assisting SME's with CE marking compliance of Medical Devices, Machinery and Personal Protective Equipment required for export to the EU.

At present three QNET clients are trapped between the Personal Protective Equipment (PPE) Directive 89/686/EEC, its proposed or non-existing standards and accredited Inspection (notified) Bodies whose services are limited to testing.

Case I

The primary challenge in this case is a (draft) product specific standard, with technical specifications that eliminate new technology 'mass produced' products manufactured by two American SME's. If this standard is published and thereby becomes official it will make it impossible for the SME's to comply with the PPE Directive requirements and export their new technology devices to the EU. This will result in losses of millions of dollars in export sales.

This specific product standard is repeatedly introduced under different names and numbers:

2001 As a draft British Standard, never published.

2007 As a draft standard by CEN standards writing organization. It received a negative review by a CEN consultant. Never published.

2010 As an in-house standard by one of the Inspection Bodies, not available publicly.

2011 Pending Draft National British Standard. Not yet published due to objections by the US Department of Commerce and ANSI.

While these draft versions have never been published Inspection Bodies do use them for compliance testing. These Bodies are unwilling or incapable of assisting clients with the alternative compliance route outlined in the PPE Directive 89/686/EEC.

The SME's have offered independent third party US expertise which was declined. They have offered to meet with the standard writing committee, which has also been declined.

The successful solution to this challenge may be one of three:

a) EU accreditation of Inspection Bodies only that are capable of performing services in accordance with all compliance routes outlined in the Personal Protective Equipment (PPE) Directive 89/686/EEC.
b) A standard that will cover both 'Mass Produced' and 'Made to Order' for new technology products and clearly differentiates between Personal Protective and Medical Intended use.
c) Two separate standards based on today's technology, one for 'Mass Produced" and one for "Made to Order".

Case II

The primary challenge in this case is the lack of an existing standard and the inability by the Inspection Bodies to perform services in the absence of an existing standard.

All Inspection Bodies whose scope of accreditation included this type of product were contacted but declined to perform services in accordance with the alternative compliance route outlined in the PPE Directive 89/686/EEC. One honestly replied that 'once a harmonised standard is not called upon so our knowledge in this area is slim'. Attempts to introduce one of these Inspection Bodies to a group of experts, of the same nationality, in order to assist with the steps required for the alternative compliance route was declined.

The American SME manufacturing this product in the US has consequently been unable to export this product to the EU while receiving orders from many EU professional clients.

The successful solution to this challenge may be one of three:

a) EU accreditation of Inspection Bodies only that are capable of performing services in accordance with all compliance routes outlined in the Personal Protective Equipment (PPE) Directive 89/686/EEC.
b) A published EU harmonized standard that covers their new technology.

Summary

QNET LLC supports the US negotiation of the Transatlantic Trade and Investment Partnership agreement with the EU; however these negotiations must address the standards and Inspection Body limitations that result in trade barriers to US SME's.

Thank you for taking note of these very case specific examples, we welcome any questions you may have.

Sincerely,

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