



## **EU COMPETENT AUTHORITY VIGILANCE SYSTEM ACCEPTANCE**

In an effort to harmonize vigilance reporting in the EU, the European Commission published Meddev document 2.12/1 rev. 5, based on the Global Harmonization Task Force November 2006 vigilance guidance document.

However, Meddev documents are not legally binding and QNET device experts realized a need to determine if all EU Competent Authorities were willing to accept incident reports based on Meddev 2.12/1 rev.5, and decided to contact all for a response to two simple questions during January 2008.

The majority of the Competent Authorities responded very quickly and volunteered 'different' requirements in their country, only five countries ignored repeated requests. Below please find the response to both questions from each country, stated in their own words.

<b>EU And EFTA States</b>	<b>Q.1: Please advise if you accept incident reports based on Meddev 2.12/1 rev. 5</b>	<b>Q.2: Can Manufacturer's Report Form be filed electronically?</b>	<b>Special requirements</b>
<b>Austria</b>	No reply to emails. Website not in English.		
<b>Belgium</b>	Do accept but the timeframe for reporting is different in Belgian legislation (superseding Meddev guidelines), namely immediately ( which means as soon as possible after the incident/near-incident where a medical device is involved in known and not after complete investigation}.	Can send all files electronically BUT according to Belgian legislation, incident/near-incident reports and safety information and FSCA concerning AIMD must be sent by certified mail. In any case we do fax an acknowledgement receipt once the reference number is generated by our database.	

<b>Bulgaria</b>	Yes	Email	May also send hard copy or fax
<b>Cyprus</b>	Yes	Email	
<b>Czech Republic</b>	Yes	Email	
<b>Denmark</b>	Yes	Yes - web submission form	
<b>Estonia</b>	No reply		
<b>Finland</b>	Yes	Email	
<b>France</b>	Yes	No	Hard copy or fax
<b>Germany</b>	Yes	Email	Plus hard copy or fax
<b>Greece</b>	Yes	Email	
<b>Hungary</b>	Yes	Email	
<b>Iceland (EFTA)</b>	Yes	Email	Requires both hard copy and email
<b>Ireland</b>	Yes	Email	
<b>Italy</b>	Yes	Email	Indicate in email if hard copy will follow
<b>Latvia</b>	No reply		
<b>Liechtenstein (EFTA)</b>	No reply – Website not in English		
<b>Lithuania</b>	Yes	Email	Email, fax or post
<b>Luxemburg</b>	Yes	Email	
<b>Malta</b>	Yes	Email	
<b>Netherlands</b>	Yes	Email	<u>Do not</u> repeat by fax or regular mail
<b>Norway (EFTA)</b>	Yes	Email	Accepts e-mail, fax or regular mail.
<b>Poland</b>	Yes	Email	

<b>Portugal</b>	Yes	Email	
<b>Romania</b>	No reply – Website not in English.		
<b>Slovenia</b>	Yes	Email	
<b>Slovakia</b>	Yes	Email	
<b>Spain</b>	Yes	Email	and/or fax also acceptable
<b>Sweden</b>	Yes	Email	E-mail preferred. Telephone and fax reports are acceptable but must be confirmed by hard-copy mail
<b>Switzerland (EFTA)</b>	Yes	Email	Fax also acceptable
<b>Turkey (Candidate State)</b>	No	Email	Hard copy and Fax also acceptable
<b>United Kingdom</b>	Yes	Yes- Web submission form after registering.	E-mail, fax or post also acceptable

Manufacturers revision of their vigilance procedures, in accordance with the Meddev. 2.12/1 rev. 5 will meet the requirements of the amended medical device directive.

Companies should be aware that the EU Competent Authorities will be sharing incident reports not only with all EU countries, but also with other parts of the world with whom they have agreements, i.e. USA, Canada, Far East (Taiwan, Hong Kong, Singapore), Australia.

This emphasizes the need for manufacturers to develop and use consistent compliance intelligence to meet regulatory requirements worldwide. The Global Harmonization Task force is working hard towards that goal which QNET tracks diligently.

Our 'Doing It Once' compliance service provides guidance on developing consistency in accordance with US, EU and Canadian regulations.

Subject to change without notice.

Compiled from information provided by the Competent Authorities.

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