EU Approval of Host Devices with Integrated Wireless Modules
Technological advances and the increased allocation of electromagnetic spectrum for advanced communications have produced a wave of new electronic and digital devices that communicate wirelessly. As a result, product manufacturers are increasingly abandoning wired communications interfaces in favor of wireless technologies that offer greater user mobility without compromising transmission speed and accuracy. But obtaining worldwide regulatory approval for products with integrated wireless modules is a complex process.

In the European Union (EU), compliance with the essential requirements of the EU’s directive on Radio & Telecommunications Terminal Equipment (also known as the R&TTE Directive) is required for all wireless transmitters, including wireless modules integrated into end host devices. Ensuring compliance with the Directive’s essential requirements is the legal obligation of any party that seeks to import or sell such devices in the EU.

However, unlike regulations in the United States that require manufacturers to obtain approval either from the FCC or an FCC-approved telecommunications certification body (TCB), the EU approval process for wireless modules offer manufacturers some flexibility in their chosen method for demonstrating compliance, including the ability to self-declare compliance with the applicable harmonized standards.

This white paper from UL is discusses the key regulatory compliance and approval issues facing manufacturers and importers of host devices with integrated wireless modules. This paper provides information on the regulations regarding the sale of host devices with integrated wireless modules in the EU and guidance on how to efficiently navigate the Union’s regulatory approval process.
Background
As of Jan. 1, 2011, the EU consists of 17 individual member “states,” constituting a single economic community of over 330 million consumers. EU regulations are intended to support the free movement of approved products between EU member states through the maintenance of a unified product approval scheme and the elimination of country-specific certifications. Since 1993 and the publication of the European Commission Guide to the Implementation of directives based on the New Approach and the Global Approach (Blue Guide), products that bear the CE Mark (Conformité Européene) are presumed to be compliant with all applicable EU specifications and requirements.

Many EU directives are based on the concept of “self declaration,” or more specifically on the completion of a EC Declaration of Conformity (DoC), from which a manufacturer or importer placing a product on the EU market declares that it meets all applicable test specifications and is legally compliant with the essential requirements of any relevant EU directives. Self-declaration allows a party to label and sell a product without performing any external, third-party testing or verification.

In the case of end host devices with integrated wireless modules, Annex 1 of the Blue Guide (“Community legislation referred to in the Guide”) specifies that product approval is achieved by demonstrating compliance with the essential requirements of “the Directive 99/5/EC of the European Parliament and of the Council relating to radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity,” also known as the R&TTE Directive. In the majority of cases for end host devices, the R&TTE Directive mandates compliance with the following essential requirements:

- Product safety, including RF exposure
- Electromagnetic compatibility
- Radio and telecommunication terminal equipment requirements

Depending on the final intended application of the end host device, there may be other European directives to consider. For example, there are a number of directives applicable to medical devices that may impose additional requirements on end host devices with integrated wireless modules operating in that context.

Key Factors
When considering the sale of end host devices with integrated wireless modules within the EU, manufacturers must consider a number of key factors essential for gaining regulatory approval under the R&TTE Directive. These factors include:

- The most appropriate approach to product certification, e.g., harmonized standards (Annex III), technical construction file (Annex IV) or full quality assurance (Annex V)
- The module manufacturer’s instructions (if these are not followed, additional testing may be required to confirm compliance)
- The named party placing the end host device on the market within the EU, which is responsible for ensuring and maintaining compliance as long as the device continues to be offered for sale

This white paper covers each of these points in greater detail. Note that product approval requirements vary on a case-by-case basis, and that the examples presented here are offered only as guidance.

The EU Certification Process
The R&TTE Directive provides three separate paths for demonstrating compliance with its essential requirements, as follows:

- Harmonized standards route
- Technical construction file
- Full quality assurance

Harmonized Standards Route
Annex III of the R&TTE Directive describes the certification process using harmonized standards. When following the harmonized standards route, manufacturers and importers should always apply the latest version of the applicable harmonized standards, since compliance with the latest version is required when the final product is placed on the market. Updated lists of standards that can be used to demonstrate compliance with the essential requirements of the Directive are published periodically in the Official Journal of the European Communities.

Under the harmonized standards route, a manufacturer or importer takes complete responsibility for ensuring that a product meets the necessary EU requirements...
as detailed in the applicable harmonized standards. How and where compliance testing is performed is at the discretion of the party placing the end host product on the market. However, the manufacturer or importer must retain all relevant documentation regarding a product’s technical specifications and compliance testing results in case future questions are raised regarding the product’s conformance.

Technical Construction File

The preparation of a technical construction file (TCF) is required for demonstrating compliance to the essential requirements the R&TTE Directive. For those cases where no harmonized standard(s) can be fully or partly applied from the Official Journal, a manufacturer seeking to demonstrate compliance through the use of TCF must engage a Notified Body (NB) or other independent third party authorized to assess compliance to relevant directives. In addition to providing assistance in the selection of appropriate test standards, a NB can provide guidance in the compilation of the TCF, and prepare an official Notified Body Opinion (either positive or negative) regarding the compliance of a device.

The use of a NB or other independent third party in the preparation of a TCF offers a variety of benefits:

1. The manufacturer is confident that a product has been tested for compliance with the provisions of the appropriate standards
2. The NB may be able to use non-harmonized test data that satisfactorily demonstrates compliance with the essential requirements of the Directive, thereby potentially reducing cost and lead time. Or, if no appropriate harmonized standards can be identified, the NB can assist in the selection of standards that can be used to demonstrate compliance with the essential requirements of the Directive
3. Even when the harmonized standards route is utilized to demonstrate compliance, the preparation of a TCF by an NB can be an effective marketing tool, since the CE mark applied to the approved product is accompanied by the NB’s reference number

Full Quality Assurance

In practice, this approach is utilized only by large manufacturers that have internal testing capabilities backed by a fully integrated quality assurance system. These facilities and systems are not common for manufacturers of end host devices with integrated wireless modules. Therefore, the full quality assurance path is not covered in further detail here.

EU Testing Requirements

As previously noted, the R&TTE Directive requires compliance with the essential requirements in three main areas: product safety, including RF exposure; electromagnetic compatibility; and radio and telecommunications terminal equipment-specific requirements.

Product Safety

Regarding matters of product safety, an end host device with an integrated wireless module intended for use in a domestic or commercial environment is typically categorized as information technology (IT) equipment, and is expected to comply with the requirements found in the latest version of EN 60950 – Information Technology Equipment. However, depending on the environment in which a device is intended for use, other safety standards may be more appropriate.

With regard to RF exposure, the environment into which an end host device will be placed is extremely important. As determined by reviewing the appropriate standard published in Official Journal of the European Union (for example, EN 62311:2008) and depending on the transmitter frequency and power range, specific absorption rate (SAR) testing may be required if a device is intended for use while placed on the human head or body. If a device is not intended for use on the human body, a maximum permissible exposure (MPE) calculation is required to determine a safe operating distance for users.

If an end host device is also intended for sale outside of the EU, the manufacturer should consider testing a product for compliance with the safety requirements under the IECEE’s CB Scheme. The CB Scheme is a system that supports the mutual acceptance of test reports and certificates by participating members, and currently provides market access to more than 50 countries worldwide. For products destined for sale in North America, the manufacturer can also choose testing consistent with the requirements of a number of available safety marks (including the UL Mark issued by UL).
Electromagnetic Compatibility

The preparation of a technical construction file (TCF) is required for demonstrating compliance to the essential requirements the R&TTE Directive. For those cases where no harmonized standard(s) can be fully or partly applied from the Official Journal, a manufacturer seeking to demonstrate compliance through the use of TCF must engage a Notified Body (NB) or other independent third party authorized to assess compliance to relevant directives. In addition to providing assistance in the selection of appropriate test standards, a NB can provide guidance in the compilation of the TCF, and prepare an official Notified Body Opinion (either positive or negative) regarding the compliance of a device.

To meet the R&TTE Directive's essential requirements regarding electromagnetic compatibility (EMC), an end host device is required to demonstrate compliance with one of the EN 301 489 series of standards published in Official Journal – Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services. Each of these wireless technology collateral standards make reference to the common technical requirements specified in EN 301 489-1.

The most common list of technologies and the applicable standards in this series are identified in the table below.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>FREQUENCY</th>
<th>ARTICLE 3.2 (RADIO)</th>
<th>ARTICLE 3.1B (EMC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSM</td>
<td>900/1800MHz</td>
<td>3GPP TS51.010-1 (EN 301 511)</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-7</td>
<td>EN 301 489-7</td>
</tr>
<tr>
<td>UMTS</td>
<td>900/2100MHz</td>
<td>EN 301 908-1 and</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 908-X</td>
<td>EN 301 489-23/24</td>
</tr>
<tr>
<td>SRD (Inc RFID)</td>
<td>9kHz to 25MHz</td>
<td>EN 302 291 and/or</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 300 330-2</td>
<td>EN 301 489-3</td>
</tr>
<tr>
<td>SRD</td>
<td>25MHz to 1GHz</td>
<td>EN 300 220-2</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-3</td>
<td>EN 301 489-3</td>
</tr>
<tr>
<td>SRD</td>
<td>1GHz to 40GHz</td>
<td>EN 300 440-2</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-3</td>
<td>EN 301 489-3</td>
</tr>
<tr>
<td>WLAN (802.11b/g)</td>
<td>2.4GHz to 2.4835GHz</td>
<td>EN 300 328</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-17</td>
<td>EN 301 489-17</td>
</tr>
<tr>
<td>WLAN (802.11a)</td>
<td>5.2GHz to 5.8GHz</td>
<td>EN 301 893</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-17</td>
<td>EN 301 489-17</td>
</tr>
<tr>
<td>Bluetooth</td>
<td>2.4GHz to 2.4835GHz</td>
<td>EN 300 328</td>
<td>EN 301 489-1 ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EN 301 489-17</td>
<td>EN 301 489-17</td>
</tr>
</tbody>
</table>

Table 1: EMC and RF Standards for Common Wireless Technologies

To meet EMC requirements, an end host device must meet both the emissions and immunity conditions defined in applicable test standards. For multi-technology end host devices, assessment with each applicable test standard is required to determine overall compliance. For example, if a device contains WiFi and GSM technology, compliance with both EN 301 489-17 and EN 301 489-7 is required.
Radio

Whether a wireless technology module has previously been tested and approved to the applicable EU requirements is a key factor in determining the radio performance tests required to demonstrate compliance with the provisions of the R&TTE Directive. A “pre-approved” integrated wireless module dramatically reduces the amount of testing required and will typically require only radiated emissions testing. However, it is important to make sure that the pre-approved module is integrated into an end host device in a manner consistent with a module manufacturer’s installation instructions. Otherwise, additional testing may be required.

If a wireless module has not been previously approved, the full suite of radio performance tests is required, as defined in the applicable standard. For a device using a non-approved GSM module, several hundred hours of testing may be required, which can be an expensive proposition!

Labeling and Declarations

The CE Mark is affixed to an end host device by a manufacturer or importer, and must be done in manner that is visible, legible and indelible. If a Notified Body Opinion has been issued, then the NB’s accreditation reference number should also be used as part of the CE Mark label.

In order to use the CE Mark, the manufacturer or importer must prepare and sign a DoC attesting to a product’s conformity with all relevant directives and standards. The DoC must be available with the end host device at the point of sale, typically as part of the product documentation or user manual. A DoC must include:

- Manufacturers’ details (company name, address, etc.)
- Product characteristics
- European standards (to which conformity is attested)
- NB identification number (if applicable)
- Legally binding signature on behalf of the organization

Additionally, the R&TTE Directive stipulates that a manufacturer shall identify any restrictions that apply to placing an end host device into service, e.g., due to licensing or no harmonized frequency bands applicable to a device. In such situations, a manufacturer must attach an Alert Symbol next to the CE mark. Additional guidance can be found on the website of the EU’s Communications Office website, www.ero.dk (click on the “Deliverables” tab at the top of the page, and then on the “R&TTE equipment sub classes” tab).

For most GSM end host devices, the Alert Symbol is not typically required unless there are other radio technologies used within the product.
Other Certification Considerations

Founded in 1999, the Global Certification Forum (GCF) provides cellular network operators with confidence in the effective and trouble-free interworking of new cellular mobile terminal devices. With the PCS Type Certification Review Board (PTCRB) setting the requirements for North America, the GCF has effectively provided the foundation for mobile cellular terminal device approvals in the EU, and is a prerequisite for European network operator acceptance.

Unlike the North American market, the challenge in Europe and other parts of the world is that mobile devices can handover between many different network operators when users travel between countries and regions. Therefore, the aim of the GCF is to provide a seamless mobile communications experience for users of cellular devices. However, unless specifically stipulated by a network operator, there is currently no requirement for GCF approval of end host devices with integrated wireless modules.

Maintaining Compliance

Using a wireless communication technology module in an end host device has many advantages. If a module is installed in a manner consistent with the module manufacturer’s requirements, minimum additional testing is usually required for product approval.

Once the manufacturer or importer has an EU-compliant product, the following considerations apply:

Updates to the Module

When a manufacturer makes changes to an approved module, consideration must be given to the impact on certification, even if the changes consist only of firmware updates. All planned changes should be reviewed by an NB or test service provider. When module changes may affect the RF performance of the end host device, the NB may suggest some form of “delta testing,” i.e., partial retests, to affirm ongoing compliance.

Similarly, manufacturers should seek guidance when an approved module becomes obsolete and a replacement module is being considered for inclusion in an end host device. Unless the RF characteristics are identical, the TCF will need to be updated to demonstrate ongoing compliance.

Updates to an End Host Product

Changes to the end host device should also comply with the original CE approval restrictions. Changes that impact the radio characteristics (including the antenna), the module used or the enclosure will almost always require additional testing. Manufacturers and importers are urged to consult with an NB or test service provider for further guidance on what additional testing might be required to maintain the original end host device approval.

Updates to Harmonized Standards

European test standards are periodically updated, or are superseded by new versions. The Official Journal periodically publishes updated standards lists for the R&TTE Directive that note the “date of cessation of conformity,” providing manufacturers with advanced notice of the need to retest their products consistent with the requirements of a revised or new standard.

End host devices can claim compliance only as long as the underlying standards are active and valid at the time when those products are placed on the market. Once the date of cessation of conformity has passed, the manufacturer of a previously approved product must demonstrate compliance with the revised or replacement version of a standard. Depending on the changes to the standard, retesting may be required.
Summary
Given the complexity of obtaining approvals for end host devices with integrated wireless modules, many manufacturers opt to retain the services of a NB or other qualified testing laboratory. NBs are typically experienced in regulatory requirements and anticipated changes, and can provide expert guidance at a reasonable cost. This path to product approval is often the most efficient and cost-effective means to achieve compliance with the R&TTE’s essential requirements.

For information about the “EU Approval of Host Devices with Integrated Wireless Modules” white paper, please contact Chris Guy, Head of Global Approvals, at chris.guy@ul.com.