



Medical Device Industry recommendation to GHTF and AHWP on Free Sales Certificate (FSC) required for pre-market approval

MD Industry Concerns

Medical Device (MD) Industry considers the requirement in several countries for a FSC for a medical device issued by the National Competent Authority (NCA) in the country of origin as unnecessarily burdensome. It has limited value in its apparent intended purpose of protecting Public Health and it often leads to delays in time to market in countries requiring such an FSC.

MD Industry is asking Regulatory Authorities to reconsider this requirement.

See Annex for details on the MD Industry Concerns.

Current situation

Certain NCAs request a Free Sales Certificate (FSC) as a prerequisite for an application for a medical device pre-market and/or import approval. This FSC - sometimes also called Certificate for Foreign Government (CFG) - has to be issued by the NCA in the country of origin, i.e., the country where the manufacturing facility is located. The rationale for this pre-requisite seems to be that, if the device is not marketed in the country of origin, it may not conform to regulatory requirements.

MD Industry Recommendations

- 1. Where an importing country performs its own conformity assessment, a FSC should not be required,**
- 2. Countries insisting on a FSC should accept a FSC or copy of the market approval/examination certificate issued by any country where the conformity assessment is based on GHTF Guidelines or internationally accepted methods, regardless of the physical location of the manufacturer.**



Annex: Detailed MD Industry Concerns

In addition to the burden of FSC pre-requisite, it may even constitute a barrier to trade or a competitive disadvantage with little Public Health benefit:

1. For medical device regulatory purposes, the country of origin is not well-defined (legal manufacturer versus physical manufacturer); final assembly may be done in countries different from where key components are being produced; this makes the country of origin principle difficult to implement,
2. Certain countries may take a comparatively long time for product approval and will not issue an FSC prior to approval; the FSC requirement places manufacturers based in those countries at a disadvantage (compared to those based in countries with faster pre-market approval systems),
3. Certain countries have limited or no medical device regulations in force. The value to public health and meaning of a FSC from such countries is therefore significantly different to those of ones issued by NCAs with a well-established regulatory system. Relying on a FSC as evidence for safety and performance of a device may therefore be misleading,
4. Local rules as well as commercial considerations may require the manufacturer to place a specially designed version of the product on the market in the country of manufacture versus the country of application, without any consequences for product safety.
5. Requiring a FSC from the country of origin may unnecessarily inhibit the flexibility of a manufacturer to shift production from one manufacturing facility to another depending on manufacturing efficiency/costs/availability of materials, etc.
6. Requirements for FSC create significant additional administrative burdens on regulatory authorities in countries of origin as well as a financial burden to manufacturers.
7. The requirement by some countries for the FSC to be "legalized" by "consularisation" or "notarization" adds significantly to the administrative burden and costs of importers. For those countries party to it, this requirement may also be inconsistent with the requirements of the Hague Convention of 5 October 1961 abolishing the requirement of legalization of foreign public documents.
8. In many cases, there is no analogous requirement for certification applied to domestic producers, thereby creating a greater burden on importers and barriers to market entry.