CANADIAN MEDICAL DEVICES SECTOR INITIATIVE

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Access to the European Common Market for Medical Devices: A Marketing Approach

Industry, Science and Technology Canada
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Access to the European Common Market for Medical Devices: A Marketing Approach

By Medical Devices Canada (MEDEC)

Health Care Products Directorate
Chemicals and Bio-Industries Branch
Industry, Science & Technology Canada

Mailing address:
235 Queen Street
9th Floor East
Ottawa, Ontario
K1A 0H5

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1.0 INTRODUCTION

Marketing outside of Canada always involves greater demands upon the business person than marketing domestically. Language, local customs and business protocols are different and may pose significant barriers to entry to foreign markets. For the manufacturer of medical devices, there has always been an added ingredient because dissimilar regulatory regimes have to be considered.

Not only must Canadian medical device manufacturers and suppliers cope with local practices and conventions but local regulators usually require that domestic product standards be met before certificates of approval and licences can be obtained.

Marketing in these environments involves developing approaches distinct from those in use in Canada. As a result, costs of doing business are usually greater until the exporter has learned how to deal with local practices. In the long term, the outcome can be very rewarding but it requires perseverance and planning. The business person who does not take time to investigate and plan an approach to a foreign market will have a longer entry period, incur greater costs and risk failure.

Before launching into any foreign market, Canadian medical device manufacturers and suppliers would be well advised to examine the comparable advantages and disadvantages of doing business there. The potential market and the strength of domestic competition should be carefully considered before plans are made.

However, once the decision has been made, a sound marketing plan outlining objectives and detailing action steps should be developed. The first step in this process is to familiarize oneself with all the elements that will have to be considered to introduce the product to the market. It also provides direction to more detailed information sources.

MEDEC has prepared this document for those in the Canadian medical device industry who are considering entering the European Common Market (EC). Its purpose is to provide the reader with a synopsis or overview of the major factors that will have to be considered by any Canadian manufacturer or supplier of medical devices contemplating an approach to this market. It also provides direction to more detailed information sources.

Moreover, it is an attempt to alert the possible exporter to those local customs and practices that might impede success. It is not intended to be an exhaustive treatment of the subject and should only be used as a guide. Success in the European market ultimately depends on how well the exporter has prepared for it.

As the European market will be undergoing significant regulatory change after 1992, it is advisable that exporters familiarize themselves with the framework and timing of the changes as these may well determine marketing decisions. While not minimizing the importance of these changes, some familiar problems will remain. All of these will require planning and action.

Whatever the choice of country of entry, the difficulties of complying with the particular regulatory regime in force, the kind of presence required and the potential costs involved will be major factors in any decision to enter the EC.

Member States of the European Community (EC)

Belgium
Denmark
France
Germany
Greece
Ireland
Italy
Luxembourg
Netherlands
Portugal
Spain
United Kingdom

2.0 THE NEW REGULATORY ENVIRONMENT

Background

Ever since its beginning, the EC has attempted to harmonize the different standards of its member states. However, the procedure for doing so was considered so awkward that standards developments in the member states continued to outstrip harmonizing attempts by the community. In 1985, the Commission White Paper on completing the Internal Market recommended a program of some 300 directives to eliminate intra - community barriers by 1992. As a result, a streamlined procedure for adopting new directives to harmonize standards was introduced.

Directives

Directives are issued by the European Council and are binding upon the members. These directives require that member states enact national laws to implement the essential requirements of the directive (see Annex I). Medical devices are included in the program and, in that regard, the EC has classified medical devices into three categories:

1. Active implantable medical devices
2. Medical devices
3. In-vitro diagnostic medical devices

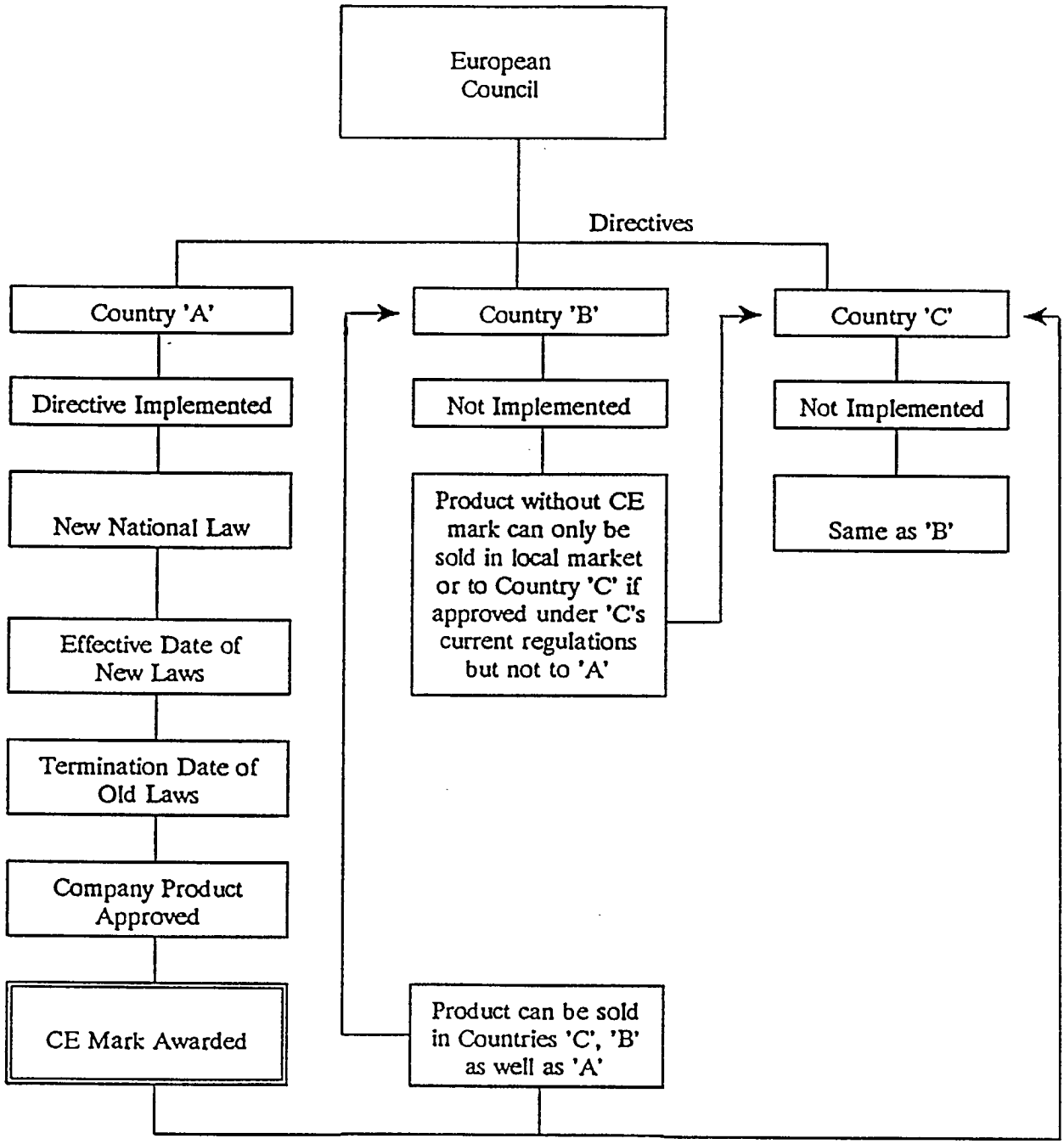
A directive (90/385/EEC) was adopted June 20, 1990 for active implantable medical devices and comes into force January 1, 1993. A proposed directive (June 21, 1991) has been issued for medical devices and one is being prepared for in-vitro diagnostic devices. In this regard, reference should be made to Annex II which sets forth the definitions of the various categories.

Process

Once a directive has been issued, it is the responsibility of each member state to modify its existing laws to conform with it. In the case of Directive 90/385/EEC concerning active implantable devices, the following timetable will apply:

1. National laws implementing the directive to be published by July 1, 1992.
2. These laws to come into force January 1, 1993.
3. Existing national laws no longer have effect after December 31, 1994.

Product Approval Plan



In fact no member state has yet passed the necessary enabling legislation to bring 90/385/EEC into operation. It is anticipated that Germany may well be the first country to do so but to this date (March, 1992) has not.

Nevertheless, member states are moving to implement the requirements of Directive 90/385/EEC by changing domestic regulations:

> *Example:* In the UK in 1991 the medical devices directorate of the Department of Health issued new quality systems documents for the Manufacturer's Registration Scheme. Manufacturers who meet the standards contained in the documents should find it possible to move smoothly to meet the quality assurance provisions of the Directive when implemented in the UK. For a definition of the transitional provisions of Directive 90/385/EEC see Annex III.

With respect to the objectives concerning medical devices and in-vitro diagnostic devices, the following timetable is suggested but should not be considered as binding.

Timetable			
Directive	**EC Enactment**	**Effective in National Law**	**Transition Period**
Medical Devices	1992	1994 - 1995	1994-95 to 1998
In-vitro Devices	1993	1994 - 1995	1994-95 to 1998

Steps

The result of all this is that any Canadian manufacturer or supplier contemplating an entry into the EC must first determine the following:

1. Is there a directive that applies to the product?

2. Has any member state passed legislation to enact the directive?

If there is no directive or no legislation has been passed in the state where approval is being sought then national laws still apply. In such event a Canadian exporter wishing to do business in several EC states must obtain approval in each one.

However, if a directive has been implemented in one state then an approval obtained under its laws will apply to all other states in the EC. The product can then be sold in any other state without further approval subject to complying with local laws governing language and labelling requirements. (See Figure on page 4 "Product Approval Plan").

Impact

Obtaining approval in a member state that has implemented a directive allows the "CE" mark to be attached to the product. The mark signifies that the product satisfies the essential requirements of the directive and may be sold in any EC state. Approval is obtained from a "notified body". Notified bodies are those recognized by member states as competent to carry out an assessment of the product.

Basis of Approval

Approval is based upon meeting the essential requirements of the directive. These requirements are written in general terms but refer to other more specific criteria, i.e., community standards. Compliance with these community or harmonized standards are deemed to be compliance with the essential requirements of the directive.

Harmonized Standards

The standards are those developed and adopted by two European standard bodies - Comité européen de normalisation (CEN) and Comité européen de normalisation électrotechnique (CENELEC) - and deemed by the EC to meet the essential requirements of a directive.

Registered under Belgian law, headquartered in Brussels and referred to as The Joint European Standards Institution, CEN and CENELEC consist not only of representatives of the 12 EC states but of the 6 countries of the European Free Trade Association (EFTA). CEN develops standards for non - electrical devices and CENELEC develops those for electrical devices.

These bodies are governed by the CEN/CENELEC agreement of 1982 and aim at implementing or complementing the standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). This may not always be possible as the international standards may:

- Not be up-to-date
- Be too prescriptive of design and manufacturing methods
- Not contain proper test procedures
- Be over-ridden by new standards

Nevertheless, with very few exceptions, the standards drawn by CEN/CENELEC reflect those of the ISO and IEC. Therefore, compliance with the international standards, will mean, in most cases, that one also conforms to the EC harmonized standards. In fact ISO 9000, international standards for quality management, forms the basis of the community's EN 29 0000 series and the EN 46 000 series relating specifically to medical devices.

3.0 THE EUROPEAN MARKET

As a means of familiarizing Canadian exporters with the opportunities in the European market, profiles of two of these markets - the UK and Germany - are set out below:

3.1 The United Kingdom Market

The UK is the third largest medical device market in Europe. After years of under-funding, the market is undergoing significant growth with an increase of 9%, 18% and 16% for 1987, 1988, and 1989 respectively. The industry employs over 20,000 people and has substantial exports.

Despite strength in many areas, the industry is under-developed in the fields of imaging, endoscopy, and dental equipment. Although much research is done in the UK, the industry has lacked funding for product development, hence products invented in the UK typically are developed and manufactured abroad.

The forthcoming restructuring of the National Health Service (NHS) is anticipated to result in new markets for medical devices. Hospitals and clinics may soon be able to procure their own equipment and supplies rather than purchase through regional supply offices. Furthermore, if practice restrictions are eased as anticipated, this may serve to develop another market serving the physician's office.

Import Status

Imports of medical devices are approximately 60% of the UK's market. This ranges from 45% for medical disposable supplies to 80% for electro-medical and X-ray apparatus. The import market has been growing and is predicted to continue, particularly in the following categories:

- Dental equipment and supplies
- ECG equipment
- Endoscopes
- Medical furniture
- Adhesive dressings
- X-ray apparatus and contrast media
- Ultrasonic diathermy
- Ophthalmic instruments
- Syringes
- Sutures

The Association of British Health Care Industries annual report (1990) indicates that imports have risen by 7% to £785.0 million in that year, with the following countries as import sources:

Country	Imports (Millions)
U.S.	£ 211.8
Germany	£ 145.3
Netherlands	£ 54.3
Irish Republic	£ 48.6
Switzerland	£ 32.5
Denmark	£ 29.1
Austria	£ 11.4
Taiwan	£ 7.2

Import Market Predictions

According to a MDIS/McGraw-Hill joint publication*, the import market is expected to continue to grow at an annual rate of approximately 5% over the next five years, with the hospital market as the largest consumer. This prediction is based on the following:

- Public hospitals are expected to invest in modernizing their facilities and equipment in order to compete for patients with private hospitals, which are of more recent vintage, hence offer more modern accommodation and services.

- Private hospitals and clinics are also expected to increase in number and scale so as to maintain their share of the patient market.

- NHS reforms in management and reduction in duplication of service are expected to release funding for needed equipment and products.

The following market sectors have been identified as growth areas:

- Diagnostic imaging
- Intensive care
- Endoscopy
- Ophthalmic surgery
- Radiotherapy

Source: H.I.M.A.

- Laser surgery
- Orthopaedics and prosthetics
- Rehabilitation and elderly care

3.2 The German Market

Prior to unification, West Germany was the largest single market for health care supplies and equipment in the EC. With unification, the German market is expected to grow rapidly as the former East German health services are brought up to Western standards.

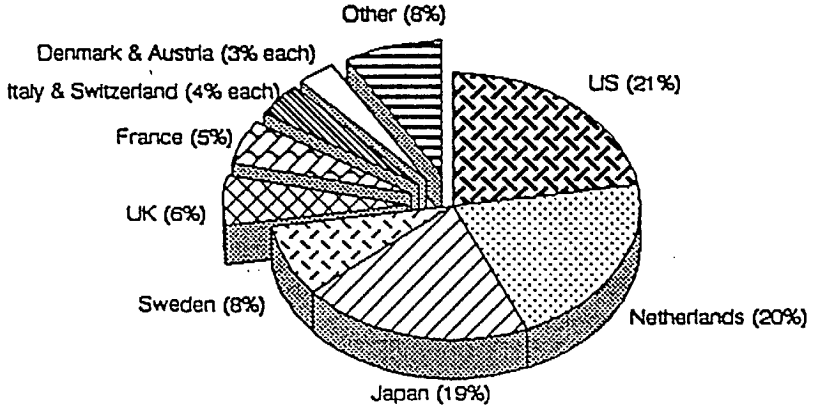
The German medical device manufacturing industry satisfies 55% of the requirements of this market. The industry is dominated by large companies but several of them are U.S. owned. In addition, certain pharmaceutical companies also provide medical devices.

Import Status

Despite Germany's strong indigenous medical device industry, the importation of medical devices has risen consistently over the past four years, from DM 1,251.7 million in 1988, to DM 1,420.0 million in 1989, to DM 1,512.7 million in 1990.

Sources of medical device imports are as depicted in Figure 1.

Figure 1
Sources of Medical Devices Imports



Source: Clinica 453, June 6, 1991 Total value: DM 1,612.7 million

Import Market Predictions

- German reunification has opened up new market possibilities. A recent report issued by the Bundesgesundheitsamt (BGA) stated that it is BGA's intent to "bring about a level of parity in equipment provisions between east and west by the year 2000". This may prove to be quite a challenge, in that the BGA estimates that equipment provision must be doubled, and 50% of the existing equipment replaced due to safety or other defects (Clinica 472, Oct. 16, 91, p. 11).

- The average number of users per large medical device per location (FRG or GDR), together with estimated costs for upgrading the east to western standards are set out in Table 1.

Table 1

Cost and Number of Medical Devices Required to Upgrade Eastern Facilities[1]

	No. of inhabitants per device ('000)		Devices required	
	(FRG)	(GDR)	Number	Price (DM m)
Cardiac catheterisation laboratories	380	2,285	35	140
CT scanners	110	515	114	171
Gamma cameras	55	275	233	163.1
Digital angiography systems	185	1,335	74	111
Magnetic resonance imaging systems	1,070	16,000	14	35
Linear and circular accelerators	475	695	11	22
Cobalt units	320	1,065	35	52.5
Kidney lithotripters	20	2,665	10	20
Other devices, technologies, surgical and analytical devices				714.6
Total			526	1,429.2

[1] Source: Clinica 433, January 9, 1992, p. 16. (1989 figures)

3.3 The EC Opportunity

Canadian exporters of medical devices to Europe have, in the past, faced a multitude of national standards that favoured domestic manufacturers and suppliers. The best approach to link with one market may not have always been the best one to use for another.

In 1993, however, the European Community (EC) will begin the creation of a single market within the community. This will be done by eliminating national standards and replacing them with harmonized standards for all suppliers throughout the community. Nevertheless, it may be some time before all member countries adopt these standards and it is anticipated that total harmonization may not be complete for some years.

For Canadian exporters of medical devices this change will pose significant challenges and open new areas of opportunity. Those exporters who have prepared for the new regulatory environment will have an important advantage over those who have not. Although it is expected that those already in the market will adjust fairly quickly, there will exist for others a window of opportunity.

A marketing approach to the EC must first consider the new regulatory environment and its significance to Canadian exporters of medical devices.

4.0 POTENTIAL COSTS OF DOING BUSINESS IN THE EC

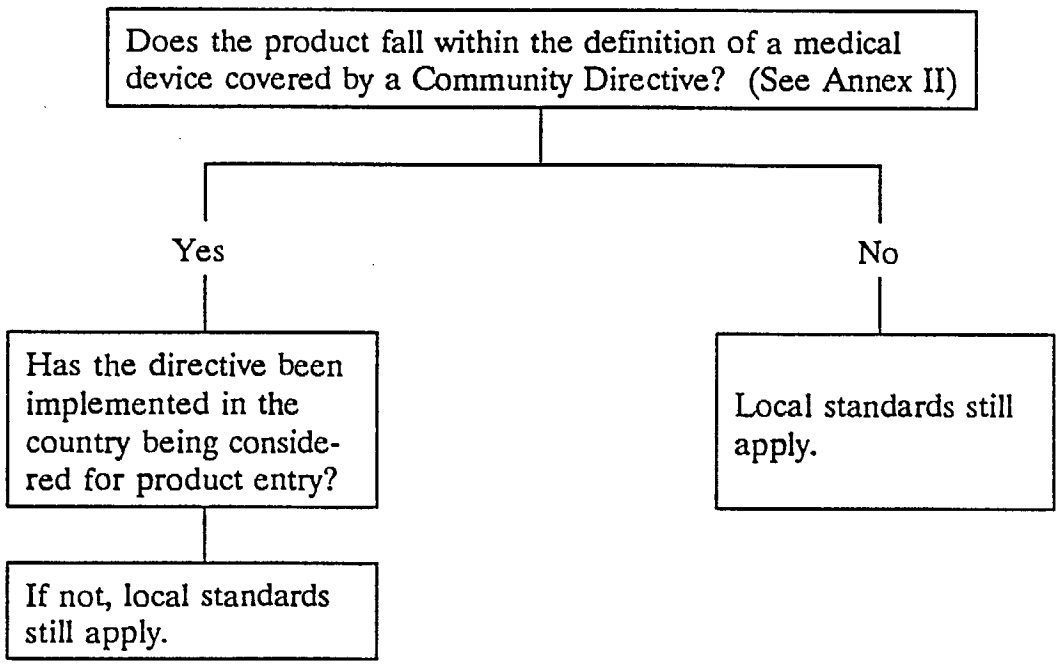
Canadian exporters contemplating an entry into the EC would be well advised to investigate thoroughly the market for their product before committing to the process of doing so.

- Will your product meet customer needs in the market?
- What is the strength of the competition?
- Are there other barriers to entry and adoption?

Factors

If the results of that preliminary investigation are favourable and a decision is made to proceed then a full cost analysis of the process of entry should be completed. This will depend on a number of factors:

1. Product Category



2. Country of Entry

Ease of entry varies from country to country.

> *Example:* The Benelux countries have traditionally been very friendly to foreign companies establishing within their borders but, by themselves, they do not constitute a major portion of the EC market. It may be wiser to choose the UK or France. However, both the UK and France have registration or certification schemes for a wide range of products which must be considered.

3. Mode of Entry

There are a number of options, e.g.:

	Pro	Con
➤ Alliance with local distributor	Fast entry into the market	May not vigorously promote product
➤ Joint venture with local manufacturer	Eases and smooths market entry; saves cost	Product could lose identity
➤ Establishing a local subsidiary	Control remains in your hands	Expensive and time consuming
➤ Selling direct	Most economical and least expensive	No local identity; will be seen as foreign product

Dealing with local customs and protocols may determine the method chosen.

Entry Options

Canadians may prefer to do business in a member state where language does not pose a problem, e.g., the UK or France. Yet if the product falls within a category that is governed by a directive and neither one of these states has passed legislation to implement it, it may be desirable to enter through another state where the CE mark can be obtained in order to gain wider market access.

Compliance Certification

Whatever the choice, a careful examination of all costs for obtaining product approval should be made. The process of approval varies with each country and its requirements and duration should be clearly understood so that costs can be accurately gauged.

> *Example:* If local regulations require an audit of quality assurance systems this may be able to be done by the Quality Management Institute (QMI) a division of the Canadian Standards Association (CSA). Additionally, CSA may also be able to certify compliance with certain technical standards. In such cases where Canadian certification is acceptable, cost savings can be considerable.

One cannot predict how certification arrangements will differ once local standards are replaced by EC standards. It will be up to the notifying body in each member state to make this determination. Notifying bodies are those organizations within a country designated by that member state to carry out the conformity assessments prescribed by the Directive. None has yet been designated but when they are, names will be published in the Official Journal of the EC. In any event, it is anticipated that the process of compliance will involve one or more of the following:

1. Manufacturer's self-certification
2. Third party audit of quality systems
3. Third party approval of product files and records
4. Third party product testing

Third parties will likely be the national notifying body or testing laboratories and quality institutes sub-contracted by them to perform tests and audits. Whether this will extend to third parties in foreign countries is not yet known but it is expected that existing arrangements with national standards bodies for certification and approval will be maintained.

> *Example:* The Quality Management Institute of the Canadian Standards Association has a number of agreements in place with standards bodies in other countries (see Annex IV).

Product Classification

The kind of conformity assessment that will be required depends upon the classification of the product. Under 90/385/EEC, there are four classes, namely:

Class	Application	Risk	Type of Certification
I	Non-sterile	Low	- Self
IIA	Sterile, Non-invasive	Medium	- Self-declaration and third-party certification of manufacturer's quality systems (EN 29002) or statistical control of products; or - Third-party certification of manufacturer's quality system (EN 29001)
IIB	Sterile, Non-invasive, Invasive natural orifice, Short-term implant, and Electro-medical	Medium	- Self-declaration and third-party certification of manufacturer's quality systems (EN 29002) or statistical control of products; or - Third-party certification of manufacturer's quality system (EN 29001)
III	Long-term implant, Active	High	- Third-party type-testing of products and quality systems approval (EN 29002) or statistical control; or - Third-party quality systems approval (EN 29001) and approval of product dossier.

Some Class I products may only require manufacturer's self-certification. This will involve a declaration of conformity and maintenance of a technical dossier for examination by the notifying body. However, some products in this class, such as sterile devices, must have a quality system for production or for final inspection and test, or must allow sample testing. Charts outlining the conformity assessment options for the classes IIA, IIB and III are found in Annex V.

Standards

The standards referred to in the Directives are only those that have been adopted by the European Commission and published in its Official Journal. These standards have been adopted by CEN/CENELEC (see Annex VI) as harmonization standards and have been issued in a Harmonization Document (HD). These standards are of various kinds, e.g.:

- Standards relating to good manufacturing practice (GMP)
- Testing procedures
- Product specific standards (specifications)

Some or all of these kinds of standards may apply. However, the product classification will indicate which ones do so. Standards relating to GMP have been adopted from the ISO series 9000 and are restated in EN 29000 and EN 45000 which relates specifically to medical devices.

Canadian makers of medical devices contemplating a European presence would be well advised to obtain certification under ISO series 9000 now if a quality system audit will be required to obtain the CE mark for the product. If product specifications apply the appropriate standards can be obtained from:

Standards Council of Canada
45 O'Connor Street
Suite #1200
Ottawa, Ontario
K1P 6N7

As already mentioned, the Medical Devices Directorate of the UK Department of Health already carries out its audits under the Manufacturer's Registration Scheme using the ISO 9000 series. Manufacturers who obtain registration under the scheme should have little difficulty in meeting the quality assurance levels required under community directives to obtain the CE mark.

In this regard, the Health Protection Branch of Health and Welfare Canada announced on February 6th, 1991 that it was proposing the introduction of ISO 9001 as the standard for the design and manufacture of medical devices in Canada.

Distribution

In France, purchasers of medical devices prefer doing business with the local sales subsidiaries of foreign firms. This ensures technical support and good after-sales service. On the other hand, in the UK it may be wiser to establish a manufacturing subsidiary because purchasing of equipment by District and Regional Supplies Officers is made from a Register of Manufacturers issued by the Department of Health. Manufacturers need not be British or even have a plant in the UK, but the product must be on the register before it can be purchased. To qualify for the list requires certification of compliance with good manufacturing standards.

The British Standards Institution (BSI) is the certifying body which audits manufacturing facilities. As BSI and the Canadian Quality Management Institute (QMI) have just completed a reciprocal agreement, it will be possible for QMI to audit a Canadian facility and satisfy the BSI requirements for sale in the United Kingdom. This program is in its infancy; mutual audits will be required initially, but full reciprocity will develop quickly.

For smaller businesses an alliance with a local distributor may be recommended. The initial costs of establishing a local subsidiary and the time line to profitability can be prohibitive. Nevertheless, close scrutiny should be given the prospective partner. Many local agents carry little inventory and may not understand the product's potential.

Still, what must be kept in mind is that, after 1992, the EC will no longer be a collection of national markets (at least in terms of regulation) but will begin to take the first steps towards integration. To view the country of entry as just one market and not as the first step to the larger EC market would be a strategic error. In such event, it would be wise to look to establishing an EC based national branch operation. At first, this could be limited to a sales person who can provide crucial information about purchasing practices and distribution channels, then the operation can be expanded to include logistics at an appropriate stage.

For smaller businesses, these costs may at first seem forbidding but this should be set against the size of the market and competition and the opportunity it presents for Canadian medical device manufacturers and suppliers. In 1989, the total EC market for medical devices was approximately $18 billion (US). There is an opportunity for the establishment of a Canadian presence in Europe.

5.0 HOW CULTURAL DIFFERENCES MAY AFFECT MARKET SUCCESS

Although the commencement of harmonization of standards after 1992 will begin the establishment of one EC regulated market, no one should consider that this will do away with the individual idiosyncrasies of national markets altogether. Obtaining the CE mark may only be the first step to doing business within the various member states of the community. Cultural and societal differences will still be the predominant determinant on how business is done within the nations making up the European Community.

It is, therefore, critical when choosing a country of entry that these key cultural differences be closely considered. To launch a product in a business environment where structures and practices are not well understood can prove not only costly but, in the end, disastrous. Although each nation may place a high value on health care and want the best equipment for its institutions, local producers may still be favoured. The customs of local purchasing bodies will not necessarily be affected by Community standards. Decisions to buy may be based on local considerations which are not readily apparent. Understanding these factors is vital to success.

Language

Language should be the most important cultural concern of any Canadian business person doing business in the EC. While English may be widely accepted as a language of the community and French may be well understood, local agencies and bodies responsible for approval and purchasing will use the native language. Therefore if one has difficulty with the local language, the use of a representative or an interpreter is recommended.

Certain countries will permit multi-language labelling. However, by law, France requires the use of French in all labelling information provided with a product. A foreign language translation may appear with the text.

Product specifications and technical terms also will have to be rendered into the national language. The process of obtaining regulatory approvals, establishing a local business operation and introducing the product to the local market will require a facility in the local language. The use of a local agent or facilitator at the investigation and planning stage is highly recommended.

Customs and Practices

Besides concerns about language, the Canadian business person must also be aware that local customs and practices may play a crucial role in early success. It is often easy to forget these differences. To assume that the approach that proved successful in Canada or even in another European country will prove successful again is wrong. Familiarizing oneself with local business practices and social habits can help avoid embarrassments that may affect business success.

> *Example:* In some countries it is not considered to be good manners to discuss business during a meal. To do so will probably offend those whose goodwill one is attempting to solicit.

Integrating into the Local Environment

Once the decision is made to enter the European market, the Canadian exporter should make an attempt to fit into the local business environment. This does not mean that one should adopt a local disguise or hide one's Canadian identity. It does mean, however, that one should consider joining local business or trade associations. A list of European medical suppliers associations and trade associations is contained in Annexes VII and VIII.

In some countries, a Canadian identity can be an advantage:

> *Example:* In the Netherlands, Canadians have the advantage of enjoying a special image that dates from the Second World War. In addition, many Dutch people have relatives who have immigrated to this country. This special relationship makes Canadians feel at home. Nevertheless, while this may work to a Canadian business person's advantage, the Dutch expect those doing business in their country to be organized and present their products in the same way as local business persons.

Particular attention should also be paid to local work habits. Hours of work differ from country to country. Length of yearly vacations may be similar to those in Canada or may, in the case of Germany, be for longer periods. In other countries, certain months of the year are preferred for vacations:

Example: In France, the month of August is a favourite time for vacation and many employees expect to be able to take time off work during that month. This makes the month of August a poor month for conducting business in France as many firms are closed during this period. To be unaware of this practice or be aware and not acknowledge it could cause embarrassment and problems.

Structures and Organizations

At least as important as being familiar with local customs and habits is understanding the business culture of the country. In many countries, titles and positions are very important. It is important that one understand the structure of the organization or body with which one is dealing.

Always seek out the person who has the authority to deal with your concerns but don't try to take short cuts by ignoring or avoiding others in the structure with whom you are required to deal. Sometimes, it is necessary to go through many preliminary steps with subordinate officials before the decision maker is reached. Taking short cuts may not only prove embarrassing but can cause failure. For a list of key government officials in some of the EC member states see Annex IX.

Accepting Local Help

Market research may have indicated that your product would be well received locally and even that it may have a distinct advantage over the competition. However, always be receptive to suggestions and recommendations from local business persons and officials that may help ease market entry. By accepting assistance from others, you not only help yourself but strengthen ties to persons who can aid if problems develop.

Local customs and habits may dictate a totally different product presentation than is used in Canada or other countries. Never consider that it is too late to make changes for they could easily be the key to success. Always remember that doing business in another country is like starting over again; nothing should be taken for granted.

Euro-Brand/Products

An interesting development that has only been hinted at so far but is expected to gain momentum in time is the evolution of a new European market that is trans-national in character. This is paralleling the new mandated or directed EC market and can be expected to give rise to Euro-brands or Euro-products that may be distinguished from national brands and products.

In the short term, however, it is not expected that Euro-brands/products will replace national products. Additionally, national brands/products (those that have a heavy local flavour or consumer preference) are still expected to represent the larger market for some time. Nevertheless, where products do not have a significant local identity, a Pan-European approach to the market would appear to be in order. Segments of the medical device industry will probably qualify for such a treatment.

In fact, Canadian exporters may have some advantage as they are used to dealing in the North American market. Caution should be exercised with such a strategy, however, and a segmented approach to the Euro-market may be advisable at the beginning.

6.0 LOCAL BUSINESS PROTOCOLS: HOW THEY CAN AFFECT SUCCESS

Business Protocols

Business protocols differ from country to country. It is as important to be aware of these as it is of cultural customs and habits.

> *Example:* In France, pharmacists have a much higher profile in the health care field than they do in other countries. There is usually a pharmacist in the distribution chain, either because the distributor is a pharmaceutical establishment or because hospital purchasing is controlled by a pharmacist. A Canadian exporter who may not deal with pharmacists in Canada will have to learn to do so in France.

Purchasing

The most important difference in protocols is the local procedure for purchasing. These vary greatly from country to country depending on the health care regime. In the UK, the National Health Service or NHS is the central structure in the provision of health care. However, the administration of the service lies with different departments depending on whether one is in England, Northern Ireland, Scotland or Wales.

In England, the Department of Health is the supervisory body. It administers the Manufacturer's Registration Scheme. This is a list of all manufacturers that comply with standards laid down under the scheme. Not all products are covered by the scheme and hence not all manufacturers need be registered.

While purchasing officials are not obliged to use the list they are strongly encouraged to do so. In this regard, purchasing in the UK is made by regional and district procurement offices. In turn these offices operate under policies decided by the National Procurement Group which is a body consisting of regional and national purchasing officials. For a list of products that require registration see Annex X.

In France purchasing is done by the hospital or by a board that represents a group of hospitals. Notwithstanding this, as the prime funding agency for health care, the French government exercises a fair degree of control over the purchasing system.

In Germany, on the other hand, there is a high degree of decentralization. State governments have authority over health care within their boundaries. The national government establishes policy but the states administer the system. German health care is characterized by a high degree of involvement by the private sector. About one-half of the hospitals in Germany are private institutions. While private hospitals do their own purchasing, public establishments are governed by elected boards who are responsible for purchasing.

A knowledge of the protocols and practices of these organizations is a first priority in launching the product.

Testing

Another example of differing protocols is clinical trials. There is a wide range of attitudes throughout the EC on such trials. In some countries, testing procedures are highly structured and must be done through designated institutions while in others a usage test by several local physicians may suffice. This, of course, will depend on the product being tested. Ensuring that you know what is required beforehand can save trouble later.

Commercial Arrangements

One should also be aware of the different kinds of commercial arrangements that are possible under the laws of member states. In the UK, agency agreements are similar to those in Canada and the U.S. In France, however, the civil code distinguishes between three kinds of agents, i.e., distributors who sell products directly to customers and two types of intermediaries.

A distributor ("concessionaire") is one who purchases goods for resale and is similar to a wholesaler. Intermediaries, on the other hand, are more like traditional sales agents as understood in Canada as they act as representatives of the product and solicit and do business in the name of the producer.

Nevertheless, French law makes clear distinctions between each type of arrangement and one should not rely upon comparisons with Canadian norms as a guide but should ensure, if entering into an agreement with a French firm or individual, that the details are clearly understood.

Another consideration to an exporter is exclusive distribution agreements and price maintenance policies. While these are generally discouraged, they may be permitted in certain nations where such restrictions are meant to ensure a high level of after - sales service. The local law should be checked before attempting to put such arrangements in place.

Foreign Investment

Government policy on foreign investment should also be a concern for the exporter. While most countries have considerably liberalized their foreign investment rules in recent years, some restrictions still apply. If foreign investment is seen as a threat to local business and employment levels, then it will be discouraged.

On the other hand, if such investment is seen as creating jobs, it will be welcomed in some countries:

> *Example:* In the UK and France foreign investors are encouraged to establish in areas that are economically disadvantaged. In such cases, incentives or concessions may be available. It is always wise, however, to seek advice on the benefits and pitfalls before committing to invest in such areas.

Travel

Travel regulations and restrictions should also be confirmed before going abroad to investigate markets. This is one area where local laws are still very important. Although restrictions on travel between citizens of member states of the EC have been relaxed, Canadians and other foreigners entering EC countries may be required to obtain a variety of travel documents, particularly if they are staying for any length of time. In some cases, proof of financial solvency may also have to be provided.

Banking

Local banking arrangements are of prime importance and should be one of the first matters attended to once the decision is made to enter the market. The choice of bank is up to you but it is advisable to seek the advice of your Canadian bankers. If transfers of currency or letters of credit are being arranged, you will need their assistance. Moreover, if your Canadian bank has a relationship with a particular bank in the country where you will be doing business, it is advisable to obtain a letter of introduction.

It is very important that one familiarize oneself with local banking practices and, in particular, the hours of operation because they vary from country to country and even from region to region.

Example: In France, banks in Paris and some other cities are closed all day on Saturday. In Paris, regular banking hours are from 9:00 a.m. to 4:30 p.m., Monday to Friday inclusive but some banks may close during the lunch hour. Banks outside Paris and other large centres are open all day on Saturday but closed on Mondays. Banking hours in the smaller centres are 9:00 a.m. to 12:00 p.m. and 2:00 p.m. to 4:30 p.m. All French banks close at noon the day preceding national holidays.

Example: In the UK, banking hours vary considerably depending upon whether one is in England, Wales, Scotland, Northern Ireland or even in the Channel Islands. In England and Wales, banking hours are from 9:30 a.m. to 3:30 p.m., Monday to Friday inclusive except for the financial district of London where banks close at 3:00 p.m. Some banks are open one night a week to 6:00 p.m. In Scotland, banking hours are from 9:30 a.m. to 3:30 p.m., Monday to Friday inclusive but some banks may close during the lunch hour. Banks are usually open one night during the week. In Northern Ireland, banking hours are 10:00 a.m. to 12:30 p.m. and 1:30 p.m. to 3:30 p.m., Monday to Friday inclusive.

Traffic and Import Regulations

If goods are being shipped into a country, a variety of documents will be required depending on the country. In some countries, an import license may be necessary. Such things as invoices, bills of lading, packing lists and certificates of origin will have to conform to local regulations. It is, of course, permissable for the importer to handle these matters independently but the assistance of brokers and agents is recommended. In some countries, there are organizations that will provide shipping, customs clearing, forwarding and other services to the importer.

Example: In the UK, there are organizations known as importers/ factors. Not only will they arrange for goods to clear customs but they will provide warehousing and shipping services anywhere in the UK. If required, they will also price goods for the local market and do factoring, i.e., they will collect the amount owing or guarantee its payment.

Market Research

In any new market a number of important items have to be considered, eg.:

- Timing of entry into the market
- Level of entry
- Nature of demand

In a foreign market that is not well understood, the necessity of research is underscored. The Canadian exporter should look closely at these and other factors to identify potential obstacles to entry as well as areas of comparative advantage.

Contacting local distributors or agents to obtain market information and data is recommended. Calling on potential customers to determine user needs should also be done. Where possible, even the local competition can be canvassed. If after all this there is still concern that not enough facts have been gathered to make intelligent and well informed marketing decisions then it is prudent to engage a local consultant.

Assessing Market Costs

It cannot be assumed that the same cost factors that apply in Canada will apply in the European market. With respect to establishing a manufacturing operation in Europe cost of goods sold may vary considerably as cost factors for material, labour and packaging may differ from Canadian norms. If local materials of similar quality cannot be obtained then they will have to be brought in from outside and probably from Canada. Additionally, many European countries, Germany specifically, impose social charges upon employers which add to labour costs. Furthermore, local rules on recycling of packaging materials and product specific labelling will have a significant impact on gross margins.

All of these items must be considered in a fresh light. One cannot assume that expected gross margins that are earned in Canada will also be earned in Europe. Of singular importance are development and marketing costs. Advertising and sales promotion will have to reflect local conditions. Before undertaking market research, all these factors should be considered so that a realistic appraisal can be made.

Pricing

How the product is to be channelled to market, i.e., through a distributor or directly, will be important in pricing as, of course, the distributor will require a mark up. It would be judicious to develop several pricing scenarios prior to market entry. Notwithstanding a preference for a distributor arrangement, the price may be prohibitive given what the competition is charging. Unless the product can be distinguished in some way such an arrangement may not be possible.

A further complication that may arise is the tendency of foreign markets to categorize products somewhat differently from our own domestic market. This may work to one's advantage but if the product is seen to fall in a lower category, a significant downward adjustment may have to be made with the attendant adjustment in cost. It may be that such readjustment is not acceptable. Examining price and price ranges for the product should always be a first order of priority.

7.0 CONCLUSION

The EC market presents a significant opportunity for Canadian manufacturers of medical devices. Nevertheless, care must be taken to consider all elements before framing an approach to that market. This document is an attempt to alert prospective exporters to those matters which should be investigated before launching a product in the EC.

Persons requiring further information should consult the publications listed in the bibliography in Annex XI. Further information may be available from:

➤ External Affairs and International Trade Canada
125 Sussex Drive
Ottawa, Ontario
K1A 0G2

- Western Europe Trade and Investment Development Division
  Telephone: (613) 995-9402

- European Community Trade Policy (Customs information)
  Telephone: (613) 995-4017

ANNEX I

EXCERPT FROM DIRECTIVE 90/385/EEC CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

Essential Requirements

I. General Requirements

1. The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

2. The devices must achieve the performances intended by the manufacturer, viz.: be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1(2) (a) as specified by him.

3. The characteristics and performance referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.

4. The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacture (temperature, humidity, etc.).

ANNEX II

EXCERPTS FROM COMMUNITY DIRECTIVE 90/385/EEC CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES AND PROPOSED DIRECTIVE OF JUNE 21, 1991 CONCERNING MEDICAL DEVICES

Editor's explanatory note:

Article 1 of Community Directive 90/385/EEC appearing immediately below contains definitions of "active implantable medical device", "medical device", "active medical device" as well as others. It was the original intention of the framers of the directive to create four categories of medical device, namely:

1. Active Implantable Medical Device
2. Active Medical Device
3. Medical Device
4. In-Vitro Diagnostic Medical Device

However, in the Proposed Directive of June 21, 1991, there is no reference to "active medical device" only to "medical device". As Directive 90/385/EEC applies only to "active implantable medical devices" and the proposed Directive of June 21, 1991 applies only to "medical devices" it is clear that the "active medical device" category has been abandoned.

Although the Proposed Directive of June 21, 1991 contains a definition of "in-vitro diagnostic device", it does not apply to this category as a "medical device" is defined as one "used on human beings" while in-vitro devices are used to examine "substances derived from the human body". A third directive on in-vitro devices is now being prepared.

Excerpt from Directive 90/385/EEC Concerning Active Implantable Medical Devices

Article 1

1. This Directive shall apply to active implantable medical devices.

2. For the purposes of this Directive, the following definitions shall apply:

   (a) "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

ANNEX II

EXCERPTS FROM COMMUNITY DIRECTIVE 90/385/EEC CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES AND PROPOSED DIRECTIVE OF JUNE 21, 1991 CONCERNING MEDICAL DEVICES
(Continued)

- Diagnosis, prevention, monitoring, treatment or alleviation of disease or injury.

- Investigation, replacement or modification of the anatomy or of a physiological process.

- Control of conception.

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means;

(b) "Active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

(c) "Active implantable medical device" means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

(d) "Custom-made device" means any active implantable medical device specifically made in accordance with a medical specialists' written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient;

(e) "Device intended for clinical investigation" means any active implantable medical device intended for use by a specialist doctor when conducting investigations in an adequate human clinical environment;

(f) "Intended purpose" means the use of which the medical device is intended and for which it is suited according to the data supplied by the manufacturer in the instructions;

(g) "Putting into service" means making available to the medical profession for implantation.

ANNEX II

EXCERPTS FROM COMMUNITY DIRECTIVE 90/385/EEC CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES AND PROPOSED DIRECTIVE OF JUNE 21, 1991 CONCERNING MEDICAL DEVICES
(Continued)

Excerpt from Proposed Directive of June 21, 1991 Concerning Medical Devices

Article 1

Legal Definitions, Scope

1. This Directive shall apply to medical devices. It also covers the accessories to which the provisions for medical devices apply.

2. For the purposes of this Directive, the following definitions shall apply:

(a) "Medical device" means any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used on human beings solely or principally in the:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap.

- Investigation, replacement or modification of the anatomy or of a physiological process.

- Control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medical devices are hereinafter referred to as "devices".

(b) "Accessory" means an article which, while not a device as defined in point (a), is required, according to the intended purpose attributed to it by the manufacturer, to enable a device to be used as specified.

ANNEX II

EXCERPTS FROM COMMUNITY DIRECTIVE 90/385/EEC CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES AND PROPOSED DIRECTIVE OF JUNE 21, 1991 CONCERNING MEDICAL DEVICES
(Continued)

(c) "Device used for in-vitro diagnosis" means any device which is a reagent, reactive product, unit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used solely or principally *in vitro* for the examination of substances derived from the human body with a view to providing information for the detection, diagnosis, control or treatment of a physiological state, of a state of health or disease, or of a congenital anomaly.

(d) "Custom-made device" means any device specifically made in accordance with a duly qualified medical specialist's written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient.

The above mentioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical specialist or any other professional user are not considered to be custom-made devices.

(e) "Device intended for clinical investigation" means any device intended for use by a duly qualified medical specialist when conducting investigations as referred to in point 2.1 of Annex 10 in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be considered equal to a duly qualified medical specialist.

(f) "Implantable device" means any device which is intended:

- To be totally or partially introduced into the human body or a natural orifice or

- To replace an epithelial surface or the surface of the eye

by surgical intervention, which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention.

(g) "Manufacturer" means the natural or legal person with overall responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market on his own behalf, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The natural or legal person who assembles, packages, processes and/or labels one or more ready-made products and/or assigns to them their intended purposes as a device with a view to their being placed on the market on his own behalf is also considered to be a manufacturer. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

(h) "Intended purpose" means the use for which the device is intended and for which it is suited according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

(i) "Placing on the market" means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully reconditioned.

(j) "Putting into service" means the stage when a device is ready for use for the first time on the Community market for its intended purpose.

(k) "Bioavailability" means the release of a substance into or onto the human body in such a way that the interaction with the body can reasonably be detected.

ANNEX III

EXCERPT FROM DIRECTIVE 90/385/EEC
CONCERNING ACTIVE IMPLANTABLE MEDICAL DEVICES

Article 16

1. Before 1 July 1992, Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

   They shall apply such provision from 1 January 1993.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

3. Member States shall for the period up to 31 December 1994, permit the placing on the market and putting into service of devices complying with national rules in force in their territory on 31 December 1992.

ANNEX IV

QUALITY MANAGEMENT INSTITUTE
A DIVISION OF CANADIAN STANDARDS ASSOCIATION

QMI Agreements with Third Parties in Other Countries*

➢ BSI, England	(M.O.U.)**
➢ KEMA, Holland	(M.O.U.)
➢ SA, Australia	(M.O.U.)
➢ SANZ, New Zealand	(M.O.U.)
➢ SIS, Sweden	(M.O.U.)
➢ TELARC, New Zealand	(M.O.U.)
➢ UL, U.S.A.	(M.O.U.)
➢ AFAQ, France	(Cooperative Agreement)
➢ DQS (DIN), Germany	(Cooperative Agreement)

QMI Agreements Currently Being Negotiated*

- ➢ AV, Belgium
- ➢ JMI, Japan
- ➢ KAITECH, South Korea
- ➢ DS, Denmark
- ➢ SII, Israel
- ➢ SQS, Switzerland
- ➢ SISIR, Singapore

* March, 1991

** Memorandum of Understanding: A full M.O.U. means that the two organizations/countries accept each other's certificates as equivalent. Cooperative agreements involve the two organizations'/countries' joint audits of each other's policies and procedures. When this process has been successfully completed, a full M.O.U. is signed.

Source: Q.M.I.

ANNEX IV

QUALITY MANAGEMENT INSTITUTE
A DIVISION OF CANADIAN STANDARDS ASSOCIATION
(Continued)

Main Address:

QMI
Mississauga Executive Centre
Suite #800
Two Robert Speck Parkway
Mississauga, Ontario
Canada L4Z 1H8
Tel: (416) 272-3920
Fax: (416) 272-3942

Other Centers:

Pacific:

QMI
5760 Minoru Blvd.
Richmond (Vancouver), British Columbia
Canada V6X 2A9
Tel: (604) 537-9455
Tel: (604) 276-1573
Fax: (604) 273-5815

Western:

QMI
Suite #710 Manulife Centre
603 - 7th Avenue
Calgary, Alberta
Canada T2P 2T5
Tel: (403) 261-4048
Fax: (403) 261-4075

Eastern:

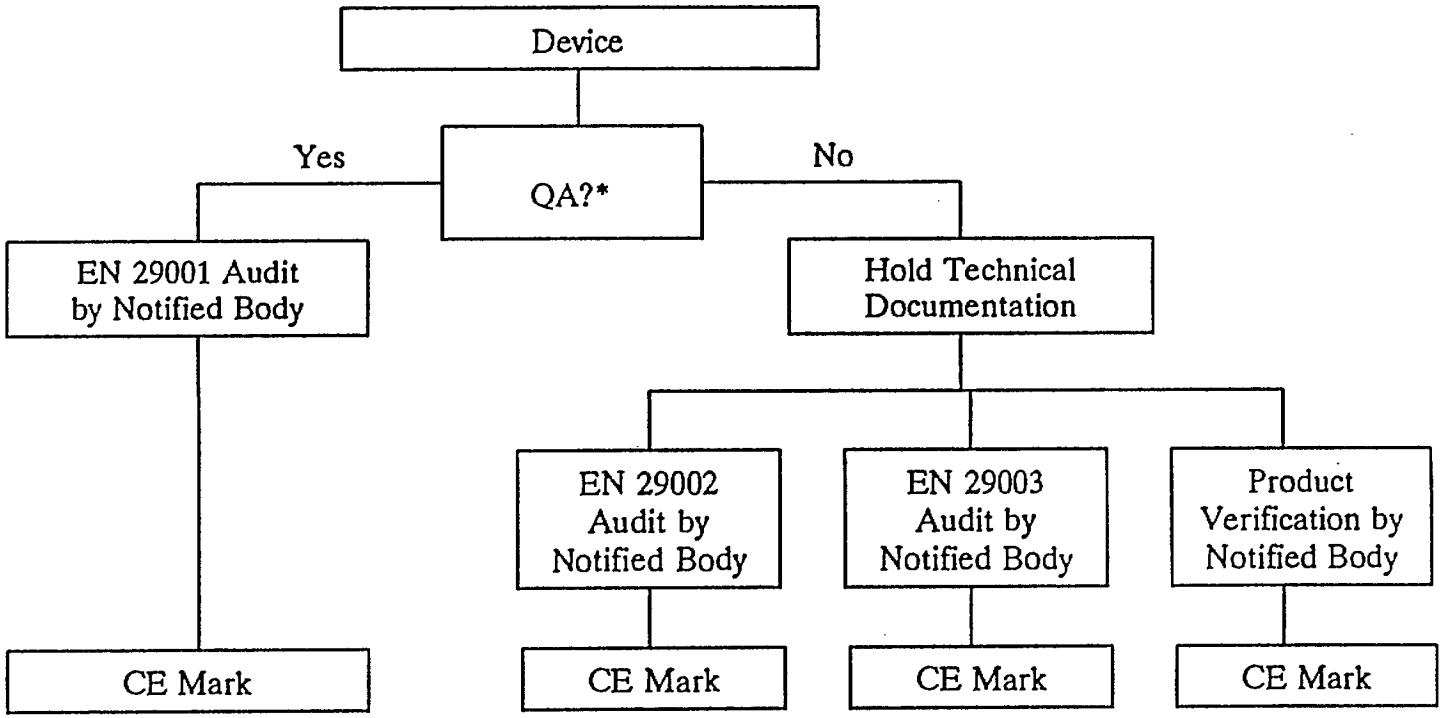
QMI
865 Ellingham Street
Pointe Claire (Montreal), Quebec
Canada H9R 5E8
Tel: (514) 694-8110
Fax: (514) 694-5001
Fax: (514) 694-0661

QMI
244 Lewisville Road
Moncton, New Brunswick
Canada E1A 2R5
Tel: (506) 858-9300
Fax: (506) 858-9302

ANNEX V

CONFORMITY ASSESSMENT OPTIONS

CLASS IIA



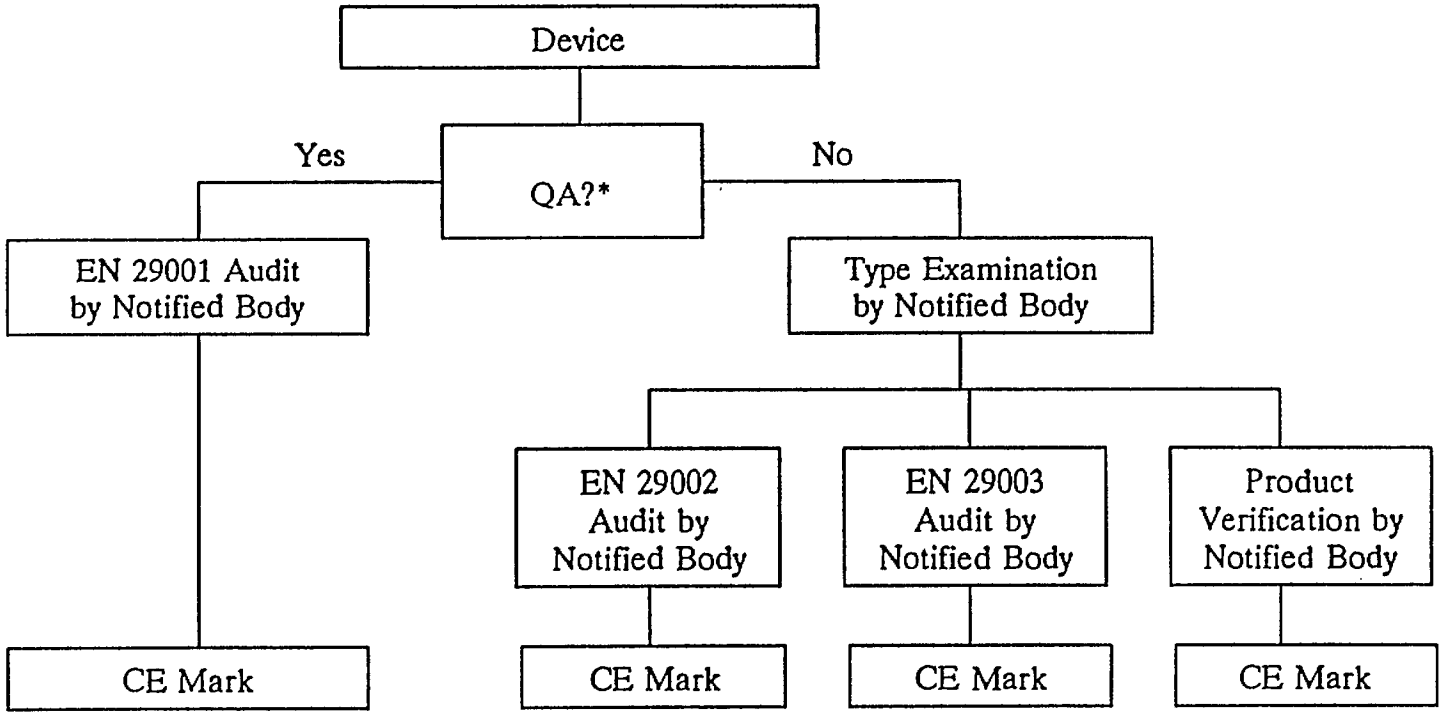
* Quality Assurance System in place?

Source: HIMA - Focus May/91

ANNEX V

CONFORMITY ASSESSMENT OPTIONS
(Continued)

CLASS IIB

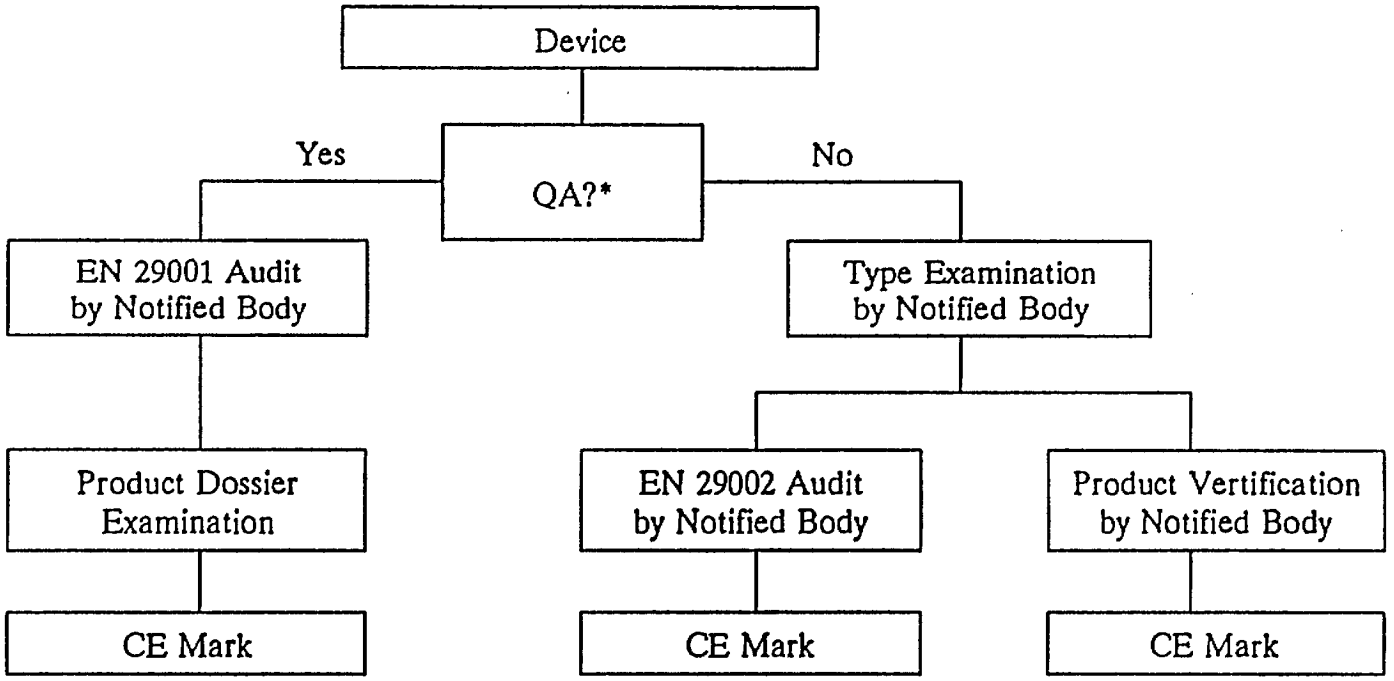


* Quality Assurance System in place?
Source: HIMA - Focus May/91

ANNEX V

CONFORMITY ASSESSMENT OPTIONS
(Continued)

CLASS III



* Quality Assurance Systems in place?

Source: HIMA - Focus May/91

ANNEX VI

CEN/CENELEC MEMBER BODIES
(Continued)

DIN
Deutsches Institut für
Normung e.v.
Burggrafenstraße 6
Postfach 11 07
D-1000 Berlin 30
Phone: 49/30/26 01-1
Fax: 49/30/26 01 (231)

DS
Dansk Standardiser Ingsråd
73, Baunegårdsvej
DK-2900 Hellerup
Phone: 45/39/77.01.01
Fax: 45/39.77.02.02

NSAI
The National Standards
Authority of Ireland
Glasnevin
IRL - Dublin 9
Phone: 353/1/37.01.01
Fax: 353/1/36.98.21

NSF
Norges
Standardiseringsforbund
Hegdehaugsveien 31
Postboks 7020
Homansbyen
N-0306 Oslo 3
Phone: 47/2/46.60.94
Fax: 47/2/46.44.57

ITM
Inspection du travail
et des mines
rue Zithe 27
B.P. 26
L - 2010 Luxembourg
Phone: 352/49/921.21.06
Fax: 352/49/14.47

NNI
Nederlands Normalisatie-
Instituut
Kalfjeslaan 2
Postbus 5059
NL - 2600 GB Delft
Phone: 31/15/69.03.90
Fax: 31/15/69.01.90

SIS
Standardiser Inskommissionen i Sverige
Tegnergatan 11
Box 3295
S-10366 Stockholm
Phone: 46/8/230.400
Fax: 46/8/117.035

SNV
Schweizerische Normen-
Vereinigung
Kirchenweg 4
Postfach
Ch-8032 Zürich
Phone: 41/1/384.47.47
Fax: 41/1/384.47.74

ANNEX VI

CEN/CENELEC MEMBER BODIES
(Continued)

ON
Österreichisches
Normungsinstitut
Heinestraße 38
Postfach 130
A-1021 Wien 2
Phone: 43/222/26.75.35
Fax: 43/222/26.75.52

SFS
Suomen
Standardisoimisliitto ry
Bulevardi 5A 7
PO Box 205
SF-00121 Helsinki 12
Phone: 358/0 64 56 01
Fax: 358/0 64 31 47

STRI
Technological Institute of Iceland
Standards Division
Keldnaholt
IS-112 Reykjavik
Phone: 354/1/68.70.00
Fax: 353/1/68.74.09

UNI
Ente Nazionale Italiano di Unificazione
Piazza Armando Diaz 2
I-20123 Milano
Phone: 39/2/70.02.41
Fax: 39/2/86.90.120

ANNEX VI

CEN/CENELEC MEMBER BODIES
(Continued)

CENELEC
Comité européen de normalisation électrotechnique
M. Jos Keestens
rue de Stassart, 35 (2nd floor)
B-1050 Bruxelles
Phone: 32/2/519.68.71
Fax: 32/2/519.69.19

National Standardization Bodies of CENELEC

OVE
Österreichischen Verband
für Elektrotechnik
Eschenbachgasse 9
A-1010 Wien
Phone: 43/222/587.63.73
Fax: 43/222/567.408

CEB
Comité électrotechnique
belge
3 Galerie Ravenstein
Bte 11
B-1000 Bruxelles
Phone: 32/2/512.00.28
Fax: 32/2/511.29.38

CES
Comité électrotechnique
suisse
Lettres: Postfach
CH-8034 Zürich
Colls:
Seefeidstrasse 301
CH-8008 Zurich
Phone: 41/1/394.91.11
Fax: 41/1/55.14.26

DEK
Dansk Elektroteknisk Komite
Strandgade 36, st
DK-1041 København K
Phone: 45/31/57.50.50
Fax: 45/31/57.63.50

AEE
Asociación Electrotécnica y Electrónica
Española
Avenida del Brasil 7
E-Madrid 20
Phone: 34/1/270.44.00
Fax: 34/1/270.49.72

Service de l'énergie de l'état
34, avenue Marie-Thérèse
B.P. N° 10
L - 2010 Luxembourg
Phone: 352/44.20.30.20
Fax: 352/44.20.51

ANNEX VI

CEN/CENELEC MEMBER BODIES
(Continued)

DKE
Deutsche
Elektrotechnische
Kommission Im DIN und VDE
Stresemannallee 15
D-6000 Frankfurt/Main 70
Phone: 49/69/6308-0
Fax: 49/69/6312-925

SESKO
Finnish Electrotechnical
Standards Association
PO Box 134
SF-00211 Helsinki 21
Phone: 358.0/69631
Fax: 358.0/692.54.74

UTE
Union technique de
l'électricité
Immeuble Lavoisier
4, Place des Vosges
La Défense 5 -
Courbevole, UTE - Cédex 64
F -92052 Paris la Défense
Phone: 33/1/47.68.50.20
Fax: 33/1/47.89.47.75

BEC - BSI
British Electrotechnical
Committee
British Standards
Institution
2, Park Street
GB - London W1A 2BS
Phone: 44/1/629.90.00
Fax: 44/1/629.05.06

NEC
Netherlands Elektrotechnisch Comite
Kalfjeslaan 2
Postbus 5059
NL - 2600 GB Delft
Phone: 31/15/690.390
Fax: 31/15/690.190

ICS - TIC
The Icelandic Council for Standardization
Technological Instiute of Iceland
Keldnalholt
IS - 110 Reykjavik
Phone: 354/1/68.70.00
Fax: 354/1/68.74.09

CEI
Comitato Elettrotecnico Italiano
Viale Monza 259
I-20126 Milano
Phone: 39/2/25.77.31
Fax: 39/2/25.773.222

NEK
Norsk Elektroteknisk Komite
Harbitzalléen 2A, Skøyen
Postboks 280
N - 0212 Oslo 2
Phone: 47/2/52.69.50
Fax: 47/2/52.69.61

ANNEX VI

CEN/CENELEC MEMBER BODIES
(Continued)

ELOT
Hellenic Organization for
Standardization
Acharnon Street 313
GR - 111 45 Athens
Phone: 30/1/201.50.25
Fax: 30/1/202.07.76

ETCI
Electro-Technical Council
of Ireland
1 Fitzwilliam Place
IRL - Dublin 2
Phone: 353/1/61.25/91
Fax: 353/1/61.17.30

EOTC
European Organization for
Testing and Certification
rue de Strassart, 33
(2nd Floor)
B - 1050 Bruxelles
Phone: 32/2/519.69.69
Fax: 32/2/510.69.71

IPQ
Instituto Português da
Qualidade
rua José Estêvao, 83A
P - 1199 Lisboa Codex
Phone: 351/1/53.98.91
Fax: 351/1/53.00.33

SEK
Svenska Elektriska
Kommissionen
Kistagangen 19
Box 1284
S - 164 28 Kista Stockholm
Phone: 46/8/750.78.20
Fax: 46/9/751.84.70

ANNEX VII

EUROPEAN CONFEDERATION OF MEDICAL SUPPLIER'S ASSOCIATION (EUCOMED)

European Confederation of Medical Suppliers' Association (EUCOMED)
Mrs. Gullan Agerbak
Boulevard Louis Schmidt 87, Box 3
B-1050 Bruxelles
Phone: 32/2/535.78.06
Fax: 32/2/535.77.06

National Contacts

Belgium
Association professionnelle des fabricants, importateurs et distributeurs de matérial et équipement médicaux (UNAMEC)
Leuvensestraat 29
B-1800 Vilvoorde
Phone: 32/2/251.05.09
Fax: 32/2/252.43.98

Germany
Bundesvereinigung Verbandmittel und Medicalprodukte e.v. (BVMed)
Hasengartenstrasse 14c
D-6200 Wiesbaden
Phone: 49/611/714.038
Fax: 49/611/719.769

Denmark
Danish Utensils Manufacturers' Association (DUFO)
Strodamvej 50A
DK-2100 København O
Phone: 45/31/20.15.15
Fax: 45/39/27.00.50

Italy
National Association of Biomedical and Diagnostic Products Suppliers (ASSOBIO-MEDICA/FEDERCHIMICA)
Via Accademica 33
I-20131 Milano
Phone: 39/2/636.23.17
Fax: 39/6/636.23.10

Ireland
Federation of Irish Chemical Industries
13 Fitzwilliam Square
Irl - Dublin 2
Phone: 353/1/765.116
Fax: 353/1/613.821

Netherlands
Nederlandse Vereniging van Fabrikanten, Importeurs, Exporteurs van et Handelaren in Medische Disposables en andere (niet-pharmaceutische) Hulpmiddelen (NEFE-MED) + Nederlandse Vereniging van Verbandstoffen-Fabrikanten(NEVERBA)
Postbus 90154
NL-5000 LG Tilburg
Phone: 31/13/654.342
Fax: 31/13/639.677

ANNEX VII

EUROPEAN CONFEDERATION OF
MEDICAL SUPPLIER'S ASSOCIATION (EUCOMED)
(Continued)

Spain
Federación Nacional de Empresas de
Instrumentación Clentifica, Médica,
Técnica y Dental (FENIN)
Covarrublas, 22 - 2 Izquierda
E-28010 Madrid
Phone: 34/1/447.12.62
Fax: 34/1/447.54.97

FENIN
Industrias Palex S.A.
Juan Sebastian Bach 12
E - 0821 Barcelona
Phone: 34/3/201.0000
Fax: 34/3/200.9841

France
Syndicat général des ouates et
pansements (SGOP)
37/39, rue de Neuilly - BP 249
F-92113 Clichy Cédex
Phone: 33/1/47.56.30.05
Fax: 33/1/47.30.25.28

Syndicat national de l'industrie
des technologies médicales (SNITEM)
39/41, rue Louis Blanc
Cedex 7292038
F-Paris La Défense
Phone: 33/1/47.17.63.88
Fax: 33/1/47.17.63.89

Portugal
Associaçao Portuguesa da Industria a/ou
Comercio de Produtos Irrecuperaveis de
Uso Clinico noa Farmaceutico
(APORMED)
PO Box 59
P-4474 Mala Cedex
Phone: 351/2/941.05.59
Fax: 351/2/948.37.60

United Kingdom
Association of British Healthcare Industry
(ABHI)
Consort House
26/28 Queensway
UK-London W2 3RX
Phone: 44/71/221.46.12
Fax: 44/71/229.47.08

Medical Sterile Products Association
(MEDISPA)
c/o Portex Ld.
Hythe
UK - Kent CT21 6JL
Phone: 44/303/260.551
Fax: 44/303/266.761

Surgical Dressings Manufacturers' Assn.
(SDMA)
70 Egremont Road
Milnrow
UK-Rochdale OL16 4ES
Phone: 44/706/41.035

ANNEX VII

EUROPEAN CONFEDERATION OF
MEDICAL SUPPLIER'S ASSOCIATION (EUCOMED)
(Continued)

Austria

Arbeitsgemeninschaft der Herstellar
Medizinischer Bedarfsartikel Österreichs
(AUSTROMED)
Testarellogasse 31/12
A-1131 Vienna
Phone: 43/222/877.70.12
Fax: 43/222/877.70.13

Norway
Leverandørforeningen for Helsesektoren
(LFH)
Postboks 169 Manglerud
N-0612 Oslo 2
Phone: 47/2/740.306
Fax: 47/2/740.303

Sweden
Swedish Association of Suppliers of
Hospital Equipment (SLF)
Sveavagen 17, 6tr
S-111 57 Stockholm
Phone: 46/8/240.700
Fax: 46/8/218.496

Switzerland

Association of Swiss Medical Suppliers
(ASMED)
Benkermergassli 20
CH-8447 Dachsen
Phone: 41/53/296.565
Fax: 41/53/296.595

Finland
Association of Laboratory and Healthcare
Product Suppliers (SAI LAB)
P.O. Box 150
SF-00251 Helsinki 25
Phone: 358/0/441.651
Fax: 358/0/496.142

ANNEX VIII

EUROPEAN TRADE ASSOCIATIONS*

Coordination Committee of the Radiological and Electromedical Industries (COCIR)
Mrs. Ellen-Urs Meyer-Schülke
ZVEI, Division Medical Engineering
P.O. Box 700969 - Stresemannallee 19
D-6000 Frankfurt/Main 70
Phone: 49/69/630.02.206 (207)
Fax: 49/69/630.23.90

EC Dental Liaison Committee
Dr. Dam Backer
Secretary
64 Wimpole Street
UK - London W1M 8AL
Phone: 44/71/935.08.75
Fax: 44/71/487.52.32

European Diagnostic Manufacturers Association (EDMA)

Mr. Gordon Tuck
Vice President
Stoke Court, Stoke Poges
Slough, SL2 4LY U.K.
Phone: 44/753 65 5151
Fax: 44/753 64 3893

Dr. Tom Morrisson
Director General
EDMA
Boulevard Louis Schmidt, 87
1040 Brussels, Belgium
Phone: 32/2/732 52 60
Fax: 32/2/732 65 11

European Federation of Pharmaceutical Industries' Assocaition (EFPIA)
Mrs. Baudrihaye
Avenue Louise 250 - boîte 91
B-1050 Bruxelles
Phone: 32/2/640.68.15
Fax: 32/2/647.60.49

European Federation of Precision, Mechanical and Optical Industries (EUROM VI)
Mr. D. Bellwinkel
Pipinstrasse 16
D-5000 Köln 1
Phone: 49/221/21.94.58
Fax: 49/221/24.50.13

* National Bodies can be accessed through these organizations

ANNEX VIII

EUROPEAN TRADE ASSOCIATIONS*
(Continued)

Federation of European Dental Laboratory Owners (FEPPD)
Mr. T.S. Roadley
Chapel House, Noel Street
UK - Nottingham NG7 6AS
Phone: 44/602/704.321
Fax: 44/602/422.675

International Association of Medical Prosthesis Manufacturers (IAPM)
Mr. Jan Thalen
rue de Lisbonne 38
F 75008 Paris
Phone: 33/14/563.03.10
Fax: 33/14/563.86.27

The European Federation of National Associations of Contact Lens Manufacturers (EUROMCONTACT)
Mr. H.M. Tillotson
Secretary-General
P.O. Box 12, Bishop's Waltham
UK - Southampton SO3 1ZN
Phone: 44/489/895.791
Fax: 44/489/895.807

The Federation of the European Dental Industry (FIDE)
Mr. J.P.A. D'Hollosy
Pipinstrasse 16
D-5000 Köln 1
Phone: 49/221/21.59.93
Fax: 49/221.24.50.13

* National Bodies can be accessed through these organizations

ANNEX IX

KEY GOVERNMENT OFFICIALS

United Kingdom

The key official for medical device regulation is:

Miss M.N. Duncan
Assistant Director (Safety and Quality)
Supplies Technology Division
Department of Health
14 Russell Square
London, WC1B 5EP

Medical advice to the Procurement Directorate is co-ordinated by:

Dr. Helen Sutton
Senior Medical Officer
Department of Health
14 Russell Square
London, WC1B 5EP

The Medicines Act established an independent committee, the Medicines Commission. The key official is:

Dr. K.H. Jones
Director
Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

The Consumer Affairs Division of the Department of Trade and Industry is responsible for the implementation of the Trade Descriptions Act (1972) and the Consumer Safety Act (1987) which includes the UK provisions on product liability. The key official is:

Mr. David Jones
Consumer Safety Unit
Millbank Tower
Millbank
London SW1P 4QU

ANNEX IX

KEY GOVERNMENT OFFICIALS
(Continued)

France

The Directorate of Hospitals (Direction des hôpitaux) and more particularly, Bureau 5D thereof is in charge of medical devices. This is headed by:

Mr. Eric Waisbord
Head of Bureau
Bureau 5D
Direction des hôpitaux
Ministère chargée de la santé et de la famille
14 rue Duquesne
75007 Paris

Germany

Key official for medical devices for key laws and regulations is:

Mr. Sengler
Bundesministerium für Arbeit und Sozialordnung
Federal Ministry of Labour and Social Affairs
Postfach 14020
5300 Bonn
Germany

The key federal institution is the Bundesgesundheitsamt (the Federal Health Office) in Berlin:

Professor E. Tschöpe
Bundesgesundheitsamt
Federal Health Office
Sesstraße
1000 Berlin 65
Germany

ANNEX IX

KEY GOVERNMENT OFFICIALS
(Continued)

Spain

Address of the key Ministries are:

Maria del Carmen Abad Luna
Subdirectora General de Evaluación de Productos Sanitarios
(General Subdirector of Evaluation of Medical Devices)
Ministerio de Sanidad y Consumo
(Ministry of Health and Consumer Affairs)
Paseo del Prado 18
28014 Madrid
Spain

Mr. Luis Reviriego
Jefe de le Sección de Tecnologías Electrónicas
(Head of Electronic Technology Section)
Ministerio de Industria y Energía
(Ministry of Industry and Energy)
Paseo de la Castellana 160
28046 Madrid
Spain

Italy

Key official for medical devices:

Dottoressa Eliana Basile
Directore, Divisione V
Presidi medico-chirurgici
Ministero della Sanitá
Direzione Generale del Servizio Farmaceutico
Viale della Civiltá Romana 7
00144 Rome
Italy

ANNEX X

HEALTH SERVICE SUPPLIES PURCHASING GUIDE (HSSPG)*

Product

Blood and solution administration sets

Clinical thermometers

Sterilization wrapping papers

Heat-sealable pouches for Contract Sterile Supplies Departments

Hypodermic needles and syringes

Luer fittings

Surgeons' gloves

* NHS supplies Officers may only buy these products if approved by DoH and listed in the guide.

ANNEX XI

BIBLIOGRAPHY

Books:

Hall, Lynne. *Latecomer's Guide to the New Europe - Doing business in Central Europe*, AMA Membership Publications Division, New York, 1992.

Reports:

Information on the European Legislation Relating to Medical Devices, Reference Documents, Contact Points, Commission of the European Communities, Directorate - General - Internal Market and Industrial Affairs, 1991.

Medical Device Approvals in Europe Today, prepared for Biometric Research Institute Inc., 1991; Series Editor C. Freeman; Monograms available:

West Germany	Spain
France	Benelux
United Kingdom	Nordic Countries
Italy	Medical Device Standards in Europe

1991 MEDEC Spring Business Conference Report on the Medical Devices Industry; Background Material prepared by Arthur D. Little, Feb./91

QMI - Corporate Quality Guide; prepared by Quality Management Institute (a division of Canadian Standards Association), 1991

Journals and Periodicals:

An Executive's guide to EC 1992, Focus, Vol. 1, No. 3, May, 1991; , published by Health Industry Manufacturer's Association (HIMA), Washington, D.C.

Clinica; published weekly by PJB Publications Ltd., London

ANNEX XI

BIBLIOGRAPHY
(Continued)

Services:

**Common Market Reports*; 4 vols., CCH Editions Limited (Fortnightly Up-dates)

**Doing Business in Europe*; 2 Vols., CCH Editions Limited (Monthly Up-dates)

***Exporter's Encyclopedia*, Dun & Bradstreet (Up-dates twice per month)

Official Publications:

ISO 9001 - Quality Systems: Model for quality assurance in design, development, production, installation and servicing; International Organization for Standardization, Geneva, 1987

91/c 160/07 - Proposal for a Council Regulation (EEC) concerning the affixing and use of the CE mark of conformity on industrial products, Official Journal of the European Community, Brussels, 1991

prEN 46 002 - Specific Requirements for the Application of EN 29 002 - for Medical devices, CEN/CENELEC, Brussels, 1991

prEN 46 003 - Guidance on the application EN 29 001/EN 46 001 and EN 29 002/EN 46 002 for the Active Implantable Medical Device Industry, CENELEC, Brussels, 1991

90/385/EEC - Directive Concerning Active Implantable Medical Devices, Commission of the European Community, Brussels, 1990

Proposal for Council Directive Concerning Medical Devices, Commission of the European Community, Brussels, 1991

I.L. No. 791 - Proposed Good Preproduction and Manufacturing Practices Regulation for Medical Devices; Information Letter, Health Protection Branch, Health and Welfare Canada, Ottawa, Feb. 6/91

* Available in Canada from CCH Canadian Limited, Toronto
** Available in Canada from Dun & Bradstreet, Toronto

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