



Emilia Romagna



Istituto nazionale per il Commercio Estero

Italian medical devices sector in EU framework

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EUROPEAN UNION

- 27 COUNTRIES
- WORLD'S MARKET N. 2 (1° USA – 3° JAPAN)
- HARMONIZATION (OF LAW AND DIRECTIVES)
- CE CERTIFICATION



EU - the medical devices sector

- **Highest production growth rates sector**
- **Increased influence on health expenditure**
- **More than 7.000 business entities in Europe**
- **350.000 employees**

EU - the medical devices regulation

Medical devices regulated under 3 directives:

- Medical Devices Directive (MDD)

all general medical devices not covered by AIMD and IVDD

- Active Implantable Medical devices (AIMD) – all active devices and related accessories intended to be permanently implanted in humans

- In Vitro Diagnostic Devices (IVDD) – all devices and kits used away from the patient to make diagnosis of patient medical conditions

The EU has proposed amendments to the current legislative framework in the area of conformity assessment (i.e. documentation, clarification of clinical evaluation requirements, post market surveillance, compliance of custom-made device manufacturers and alignment of the original medical devices directive 90/385/EEC)

Starting Block : March 21st 2010

European Union

Marketing Requirements:

- **User Service manuals in 6 - 7 languages**
- **Catalogues in English, French, German**
- **Declaration of CE Conformity**

European Union

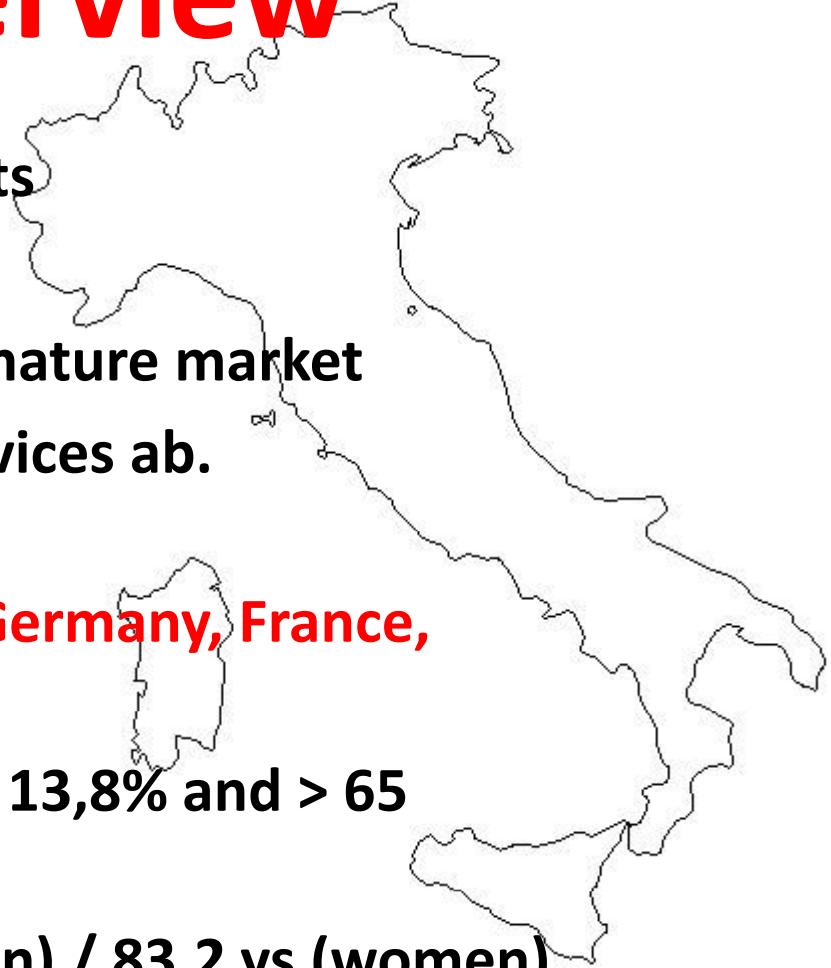
- **The top 3: Germany, UK, France in 2007**
- **Germany (12,9 billion US \$); world's 3rd largest medical device market**
- **UK (4,9 billion US \$); high price market**
- **France (7,14 billion US \$); only French accepted (source: Episcom France dec. 2007)**

EU Medical Equipment market by category 2005 – 2006 in US \$

	2005	2006
Medical X ray film	97,3	100,7
Surgical gloves	53,5	55,4
Medical, surgical, sterilisers	24,3	25,2
Wheelchairs	43,8	45,3
Contact lenses	116,8	120,8
Medical equipment	2.413,00	2.497,5
Electromedical equipment	554,6	574,0
Syringes, needles, cathethers	613,0	634,4
Dental Instruments & Appliances	116,8	120,8
Ophtalmic Instruments & Appliances	77,8	80,6
Other medical & Surgical Instruments	1.046,0	1.082,6
Therapy Apparatus	214,1	221,6
Orthopaedic & Prosthetic Appliances	929,2	961,7
Medical X-ray, Alpha, Beta,Gamma Ray equipment	496,2	513,6
Medical Furniture	73,0	75,5
Total	4.865,0	5.035,3

Italy Overview

- Population: 66 million inhabitants
- Diversified industrial economy
- Italy is an economically strong, mature market
- Values of Imports goods and services ab. 400billionUS\$
- Major import trading partners: Germany, France, Netherlands, UK
- Demographics: Ageing pop. 0-14 13,8% and > 65 21,2%
- High life expectancy: 77,6 ys (men) / 83.2 ys (women)
- 20 regions



Italian market's characteristics

- Italy has the 5° largest GDP in Europe
- Average GDP growth (2000 – 2006) is 4,4%
- **Italy is ranked as the 4° largest market in Europe and the 7° largest market globally for medical devices**
- Italian market for med. equipment is about 5.453,00 millions USD\$
- Growing market 4,8% annual growth rate for medical devices
- **The Italian Government is the primary purchaser of medical devices (77% of sales)**
- Private healthcare is 23,6% of italian market
- Major multi-national and smaller businesses are both present in Italy

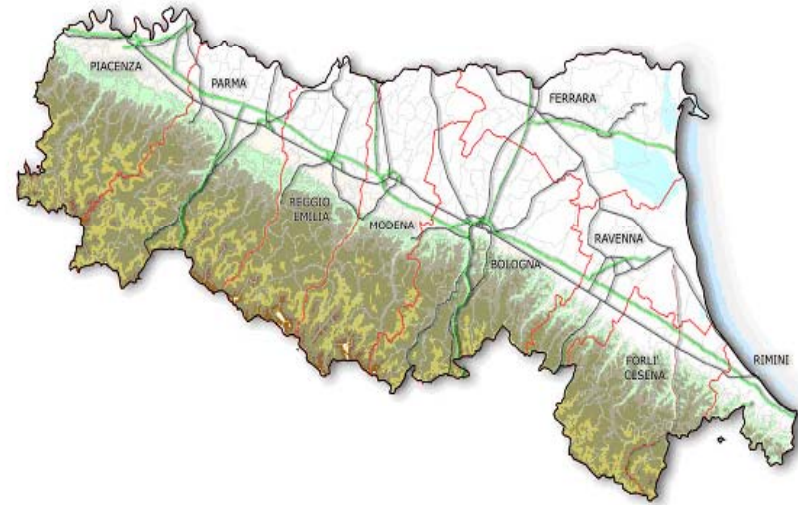
Italian obstacles and Issues

- **Long payment periods (average 280 days)**
- **Highly price sensitive market**
- **Distribution system could heavily affect the final price of the product**
- **Eg. Cost of your product + 20% V.A.T. + transportation + distribution system 60 / 100% Mark Up.**

Emilia Romagna's characteristics

Demography:

- Pop. 4.337.966 inhabitants
- Age (average) 44,85 years
- High life expectancy: 79,14 (men)
84,40 (women)



Health care companies

The health care system of Emilia-Romagna Region includes: around 2,200 companies and 51,372 employees (ISTAT 2001)

ER region is specialised in the construction of electro-machines devices and medical tools, respectively 41.7% and 23.5% of the total employment in Italy

Emilia Romagna Biomedical

companies per sub-sector - *Source: MediMap analysis on ISTAT data 2001*

<i>Subsector</i>	<i>Local units</i>	<i>%</i>
Electro-medical devices	119	5,4
Medical devices	143	6,5
Dental prosthesis	1,396	63,6
Orthopaedic prosthesis	107	4,9
Optics	132	6,0
<i>Total wide biomedical</i>	<i>1,897</i>	-
Medical devices trade	297	13,5
Total biomedical	2,194	100,0

Emilia Romagna Biomedical

employees per sub-sector (Source: MediMap on ISTAT data 2001)

<i>Subsector</i>	<i>Local units</i>	<i>%</i>
Electro-medical devices	2,206	19,6
Medical devices	3,126	27,8
Dental prothesis	3,038	27,0
Orthopaedic prothesis	686	6,1
Optics	665	5,9
<i>Total wide biomedical</i>	<i>9,721</i>	-
Medical devices trade	1,521	13,5
Total biomedical	11,242	100,0

Path of cooperation with Emilia Romagna Biomedical Cluster

- **Very high experienced small manufacturing firms**
- **Business matching for trade and industrial cooperation**
- **A strong platform (geographical and cultural) for the Mediterranean Area**

Contacts



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