IV. NEW AND GLOBAL + OLD APPROACH PRODUCT LEGISLATION:

A. Standard questionnaire to be filled for each sector individually:

***Sector*: Medical Devices**

1. Harmonisation of laws including technical regulations

1.1. Legal basis

- **References (and copies) of the publication of acts and decrees transposing Directive(s) …….. into the national legislation of your country:**

- Regulation on Active Implantable Medical Devices transposing Directive 90/385/EEC was published in the Official Gazette dated 12 March 2002

- Regulation on Medical Devices transposing Directive 93/42/EEC was published in the Official Gazette dated 13 March 2002

- Regulation on In Vitro Diagnostic Devices transposing Directive 98/79/EC was published in the Official Gazette dated 14 October 2003

The process of exchange of opinion with the European Commission on the concerned Regulations is continuing.

- **Date of entry into application of the national measures transposing the Directive:**

"Regulation on Active Implantable Medical Devices" – entered into force on 31 December 2003.

"Regulation on Medical Devices" – entered into force on 31 December 2003.

"Regulation on In-vitro Diagnostic Medical Devices" – entered into force on 14 April 2005.

- **If not yet transposed, please indicate the state of play, expected timing, steps to be undertaken, difficulties encountered (if any):**

NA

1.2. Responsible authority

- **Name and contact details of the competent authority (government, ministry, department, service) and person(s) in charge of transposing the Directive into national legislation**

Mechanical Engineer Selma BEYZADEOĞLU
Ministry of Health
Directorate General for Curative Services
Market Surveillance Section

1.3. Notified bodies

- **Has your country the intention to notify conformity assessment bodies for the Directive? If so, could you already identify these bodies (name, and contact details) and indicate the conformity tasks (products and modules) that they will be entitled to perform**

Two institutions have applied to the Ministry of Health to be notified as the conformity assessment bodies in the field of medical devices. The MoH has examined the applications and informed the institutions about the requirements stated in the "Communiqué on designation and notification of notified bodies working in the field of medical devices, active medical devices and *in vitro* diagnostic medical devices" published in the Official Gazette No. 25289, dated 14 November 2003.

2. Implementation

2.1. Participation in Standing Committee and Experts' Group

- **Name, function and contact details of the representatives (and their alternates, if any) of your country's governmental authorities designated or to be designated to represent your country in the meetings of the standing committee and experts' group established under the Directive:**

Mechanical Engineer Selma BEYZADEOĞLU
Ministry of Health
Directorate General for Curative Services
Market Surveillance Section

2.2. Implementing structure

- ***Responsible authority central/local:***

  Name and contact details of the competent authority (government ministry, department, service) and person(s) in charge of implementing the provisions of the Directive in the territory of your country:

Mechanical Engineer Selma BEYZADEOĞLU
Ministry of Health
Directorate General for Curative Services
Market Surveillance Section

- ***Implementation:***

  - Explain how implementation of the Directive in your country will be ensured (monitoring and control tools: market surveillance and others)

  - Explain how market surveillance is carried out and on which basis

  - Resources available: specify the number and qualification of personnel designated for market surveillance activities (divided in office staff/field personnel)

  - Cost: What budget will be provided for market surveillance activities? How will this be financed*?*

The implementation of the abovementioned Regulations is ensured in accordance with the provisions of the of Law No. 4703, the "Principal Law on Health Services No. 3359", Law No. 181 on the Organisation and Missions of the Ministry of Health".

The MoH has developed its 'Market Surveillance Strategy' in which the priorities of Market Surveillance activities were streamlined. The MoH will perform market surveillance activities in the field of all medical devices by its personnel consisting of 100 inspectors both in the Central and Provincial Directorates.

An amount of 312,500 Euro's has been allocated for market surveillance activities in the budget of the MoH.

- *Methods of enforcement:*

  - What means/methods will be available in your country for enforcing compliance with the Directive(s)?

  - Which are the reactive methods available?

  - *Rights* of the authority: What are the powers of the authority?

  - Penalties: which will be the penalties applicable to violation of the national implementing measures?

The provisions of Law No. 4703 and the implementing regulations of the Law as well as those of all three relevant Regulations on medical devices are applied. Additionally, the provisions of the Turkish Criminal Code No. 5237 are implemented according to the nature of the action. The main penalties in the abovementioned legislations are as follows:

- Administrative monetary penalties
- Recall of the products

3. Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance

Please provide information on the relevant regimes for the products in this sector:

- **short description and**
- **further evolution.**

The analysis of the samples collected through market surveillance is carried out by the Refik Saydam National Hygiene Centre.