Awtorita' Maltija dwar l-i Standards
It-Tieni Sular, Binja Evans
Triq Merkanti
Valletta VLT 1179
Malta

Tel: (+356) 21 242 420
Fax: (+356) 21 242 406
Email: info@msa.org.mt
URL: www.msa.org.mt
Reg. No.: MT 1515-0502

Chairman: Ing. Francis E. Farrugia

Malta Standards Authority
Second Floor, Evans Building
Merchants Street
Valletta VLT 1179
Malta

Certificate No.
FS 80769
MSA EN ISO 9001:2000

RECAST OF THE MEDICAL DEVICES DIRECTIVES ADDITIONAL COMMENTS

Entity: Malta Standards Authority
Role: National Competent Authority for Medical Devices in Malta
Contact Persons: Mr. David Pulis – david.pulis@msa.org.mt
Mr. Tristan Camilleri – tristan-charles.camilleri@msa.org.mt

Notice: These comments represent the opinion of the Malta Standards Authority only. Malta's official consolidated position will be prepared later on.

Hereunder please find additional comments that we would like to be taken into consideration in the next revision of the MDD:	
Subject:	Hospital beds, wheelchairs and patient hoists are normally classified as Class I medical devices. It has been noted from vigilance data from recent years that these types of devices are causing large amounts of incidents. According to our data, there is a high probability that incidents with these devices result in deaths or severe injuries.
MSA suggestion:	Discussions should be held on whether it is worth to reclassify these types of devices in a higher class or at least request Notified Body intervention only for these classes. Secondly, and most important, we believe that the MDEG-Vigilance Group should be responsible for watching out for trends in incident type and frequency.

Subject:	**Notified Body Language Requirements** – The Directive currently requests that "records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the

	Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body" (Article 11, paragraph 12). This means that a manufacturer in Malta would need to keep technical documentation in English or Maltese. One must keep in mind that there are no Notified Bodies in Malta designated under the Medical Devices Directives. It has been recently brought to our attention that since there are no direct requirements on the language to be used by Notified Bodies, some Maltese manufacturers were told by their Notified Bodies that all correspondence will only be done in the official language of the Notified Body. This is obviously creating an added burden on manufacturers since they would then have to translate all correspondence back into English or Maltese.
MSA suggestion:	Would it be possible to introduce an obligation for Notified Bodies to correspond at least in English with clients from other Member States?

Subject:	**Re-Branding** – Some questions in the recast questionnaire highlighted the problem of devices manufactured outside the EU. There is a general conception that devices manufactured inside the EU are safer than those manufactured outside the EU. It is a fact that there is a price difference as well between devices manufactured inside the EU and outside the EU. However, the phenomenon of re-branding is abusing this situation to the detriment of consumers. CE-marked devices are legally being imported from outside the EU but their packaging is legally being changed in order to change the legal responsibility for the product and claim that it was made in the EU. The revision of the Directives according to Directive 2007/47/EC will only contain references to the manufacturing site in Annex II, section 3 (for the full quality assurance module) and in Annex VIII, Section 3.1 (for custom-made devices).
MSA suggestion:	We feel that a reference to the manufacturing site should be included in the information to be provided both on the label and instructions for use of the device in Annex I, Section 13.

Subject:	**Definition of Manufacturer for Custom-made Devices** – The definition of a manufacturer of any medical device does not require manufacturers to

	be appropriately qualified in their field, as long as they fulfill their legal obligations. It has been brought to our attention that, in Malta, manufacturers of custom-made dental appliances are regulated by other health-related regulations that ask for manufacturers to be qualified professionals (known as dental technologists) and registered in a European Register List for Professions Complementary to Medicine. This situation is contradictory in essence since the Directive states that anyone can manufacture custom-made devices, even if he is not qualified. The same situation may be found in other sectors of medical device manufacturing.
MSA suggestion:	Just like products placed on the EU market must comply with all applicable legislation, we should discuss whether it is appropriate to extrapolate such requirement on manufacturers as well, i.e. request that persons manufacturing medical devices also comply with the requirements related to their profession.

Subject:	**Transparency for custom-made devices** – In the next revision of the Directive (March 2010), the Annex VIII Statement shall be made available to the named patient upon request (Article 4.2).
MSA suggestion:	In order to increase transparency between the manufacturer, prescriber and patient, our national industry is strongly requesting that the presentation of the Annex VIII statement to the named patient becomes a compulsory legal obligation. This situation is having an effect on safety as well. Due to the lack of transparency, manufacturers are not being given the true identity of the patient by the prescribers, with the excuse of confidentiality. This means that manufacturers cannot fully carry out their responsibilities under the Directive, especially when after 2010 they will be requested to carry out post-market surveillance as well. It is suspected that the patient is normally not aware of his right to demand information on the manufacturer of the device and the real cost of laboratory fees.

Subject:	**Timeline for Recast** – Directives 93/42/EEC and 90/385/EEC will be revised in March 2010 and we are currently in the last part of the Transposition period. A series of consultations with stakeholders has just ended and economic operators are now getting ready for the March 2010 changes. Some impacts will only be observed when the changes effectively take place. At the same time, the revision of the New Approach has been finalized and must come into effect in 2009. This again will present some regulatory changes to what stakeholders were expecting for 2010. Moreover, we now have yet again series of consultations on a Recast of the Directives. The questionnaire was extremely detailed and vast and some questions will require specific consultations just on them. When news of the recast of the MDD was published on the Commission's website, national media followed suit and just published the information they found. However, nowhere was it emphasized that this recast will not affect the transition towards March 2010.
MSA suggestion:	In order to avoid confusing stakeholders and allow them enough time to prepare for the March 2010 revision, it is strongly suggested that no further proposals are introduced before March 2010, except for changes resulting from the revision of the New Approach. Moreover, it should be clearly explained to stakeholders that this questionnaire will not undermine the March 2010 transition process.