EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) REGULATIONS 2008

2008 No.2936

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the Instrument

2.1 This instrument amends the Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative content

4.1 The current regulatory framework for medical devices has been in operation sinc1998. Whilst it has operated satisfactorily, the Commission proposed a number of regulatory changes, in the light of experience, to strengthen the regime and improve implementation to continue to safeguard public health and to continue to maintain public trust and confidence in the regulatory framework.

4.2 The main objective of the amendments to the Directives are to better specify the obligations of manufacturers, notified bodies and authorities with particular respect to the key issues of conformity assessment, clinical evaluation and post market surveillance, This is in order to continue to ensure the highest level of safety, to ensure access to the market and to allow for a smooth functioning of the legal framework. Additionally, a legal amendment was needed to allow for more openness and transparency towards the public and for clarifying to what extent specific products fall in the scope of the legislation. The Directive also creates a basis for the Community to participate in global activities on regulatory convergence, as they exist in the form of the Global Harmonisation Task Force for Medical Devices (GHTF) in order to ensure that Europe's position and regulatory framework is fully taken into consideration.

4.3 Finally, the Directive makes consequential amendments to the Active Implantable Medical Devices Directive to bring it into line with the Medical Devices Directive. There is also a small amendment to the Biocides Directive to exclude In Vitro Diagnostic Medical Devices because of an oversight during the negotiations of the IVD Directive. The Directive does not make any consequential amendments to the In Vitro Diagnostic Medical Devices Directive.

5. Territorial Extent and Application

5.1 This instrument applies to England, Wales, Scotland and Northern Ireland.

6. European Convention on Human Rights

6.1. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

7.1 Purpose and Intended Effect of Measure

The proposal amends the two Directives in a way that clarifies existing requirements to ensure better implementation across the Community. This will bring clarity to industry, the regulators and public health benefits. Key amendments cover areas such as;

- **Clinical data and evaluation**
  In order to clarify and enhance the provisions on clinical evaluation, modifications are made to a number of the Articles and to the relevant Annex concerning clinical data and its evaluation and to various references to clinical data within the provisions of the Directive, This includes a new definition of clinical data and provision for data to be included in the European databank. In addition, a manufacturer will need to have in place a post market clinical follow-up as part of a post market surveillance plan.

- **Definition of Medical Device**
  The definition now states that software intended by its manufacturers to be used specifically for diagnostic and/or therapeutic purposes are now regarded as medical devices in their own right.

- **Measures to increase transparency**
  Provisions on confidentiality, which previously provided for all information obtained under the Directive as being confidential, have been relaxed, to allow certain information on all devices to be made available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices. In addition, there is a provision to allow for consideration of user information being provided in electronic form.

- **Clarifications regarding medicinal products / medical device provisions** Devices that incorporate as an integral part a medicinal product or stable blood derivative are required to be reviewed by a Notified Body in consultation with a national authority for medicines or the European Medicines Agency (EMEA) as appropriate. These provisions which are currently contained in Annex I Section 7.4 of the Medical Devices Directive are modified to clarify both the role of the Notified Body and the relevant authorities.

- **Classification Rules**
  During negotiations, the Council Working Group reached a consensus to reclassify upwards from Class IIa to Class IIb disinfectants for invasive medical devices. This will mean manufacturers having to produce a design dossier for verification by their Notified Body. Stand-alone software is considered an active medical device. All surgically invasive devices intended for transient use are in class IIa unless they are intended for use with the central nervous system then they are class III. In addition all devices specifically for X- ray diagnostic imaging are class IIa.

- **Custom-made devices**
  Custom made device manufacturers will now be required to review and document experience gained in the post production phase and to set up a post market vigilance system of reporting to authorities, as already in place for other devices. In addition, a requirement is introduced that the 'Statement' of conformity produced by the manufacturer should be available to the named patient for whom the device has been manufactured.

- **Amendment of other Directives:**
  Modification of the Active Implantable Medical Devices Directive to bring it into line with the Medical Devices Directives. In addition modification of the Biocides Directive to exclude In -Vitro Diagnostic Medical Devices Directives from its scope in line with the other Medical Devices Directives.

7.2 The existing guidance on the Regulations will be updated and published on the MHRA website. There will also be cross references to guidance produced by the European Commission.

The Agency has already run a Conference on aspects of the Amendment Directive for manufacturers and is scheduled to repeat the exercise early 2009. Information will also be disseminated to those stakeholders with an interest.

7.3 The Regulations were consolidated in 2002. The Commission have embarked on a public consultation to recast all the medical devices Directives. This should eventually result in new amending Directives and a further consolidation exercise will be considered when that Directive is transposed. Timetable unclear but could be 2013.

8. Consultation Outcome.

8.1 The Public Consultation closed on the 15th August 2008. During this period four organisations/stakeholders contacted us with their views. Copies of which are at Annex B of the Regulatory Impact Assessment. Throughout the initial stages of the negotiations in Europe and through to the public consultation, stakeholder's views were taken into account through regular meetings with Policy staff at MHRA. A questionnaire was devised and sent to stakeholders to help accumulate costs for the RIA as well as site visits, which were undertaken by policy staff during the public consultation process. This proactive and successful approach is apparent by the low number of questioned responses received during the public consultation period.

9. Guidance

9.1 A mini consultation exercise will be conducted through the British Dental Association to gain the views of Dentists on the best way to implement the guidance for the statement for custom made devices. Interpretation documents will also be published by the commission.

10. Impact

10.1 The impact on business, charities or voluntary bodies is calculated to be in the region of £1.4m.

10.2 The impact on the public sector is that any additional costs to MHRA are either already covered for instance in the existing enforcement systems that are in place or will be catered for within existing budgets.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people the approach taken is although 70% of the medical devices sector are small firms, the impact of the proposed changes should be minimal because they are mainly housekeeping measures or putting existing practices on a formal footing. Proposals which will impact on SME's are :

- Reclassification of disinfectants, which will necessitate an additional assessment by a notified body, and the new clinical data requirements, which encourage more clinical trials to be undertaken. However, the additional costs will be minimal and the clinical trial requirement is not an absolute obligation that can be addressed by other means.

12. Monitoring and Review

12.1 Throughout the process of the revision of the Directive regular stakeholder meetings have been held and will continue to do so, this will enable us to monitor the changes and their impact on our stakeholders. Additionally the European Commission are in the process of deciding if a

recast of the Directives will begin, this will in turn review these amendments of the Directive which come into force in March 2010 and which we are transposing into UK Regulations through this process.

13. Contacts.

R.M. Gutowski at the Medicines and Healthcare products Regulatory Agency Tel: 0207 084 3253 or e-mail: Richard.gutowski@mhra.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
MHRA	**Impact Assessment of Directive 2007/47/EC,Council Directive 90/385/EEC,Council Directive 93/42/EEC,Directive 98/8/EC**	
Stage: Final	**Version: 13**	**Date:12th November 2008**

Related Publications: http://www.berr.gov.uk/files/file10462.pdf
http://www.berr.gov.uk/whatwedo/sectors/biotech/healthtech/metrics/page46980.html

Available to view or download at:
http://www.mhra.gov.uk/Howweregulate/Devices/Regulatorynews/index.htm

Contact for enquiries: Maxine Marshall **Telephone:** 0207 084 3260

What is the problem under consideration? Why is government intervention necessary?

The current regulatory framework for medical devices has been in operation since 1998. Whilst it has operated satisfactorily the Commission following a review of the Directives in 2002 proposed a number of regulatory changes, in the light of experience, to strengthen the regime and improve implementation and communication amongst Member States and to continue to safeguard public health and to maintain public trust and confidence in the regulatory framework. This resulted in this Amendment Directive.

What are the policy objectives and the intended effects?

The amendments to the Directives are to better specify the obligations of manufacturers, notified bodies and authorities with particular respect to the key issues of conformity assessment, clinical evaluation and post market surveillance, in order to continue to ensure the highest level of safety, to ensure access to the market. Other amendments are needed to allow greater transparency, encourage global co-operation and clarify specific products fall within legislation. The proposal also amends the Biocide Directive to take the IVDS out of its scope.

What policy options have been considered? Please justify any preferred option.

Option 1.Do nothing. There are no benefits in that this would disadvantage the UK medical devices industry as procedures would not be uniform throughout the community Option 2. Introduction of voluntary arrangements and guidance then transpose the Directive.Option 3. Implement the Directive by an amendment to the Medical Devices Regulation 2002. The new requirements should be of benefit to manufacturers in the long term, it should lead to greater clarity in the way the Directive works. It would also mean that the UK would not be subject to infraction proceedings due to non implementation.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The proposed amendment Directive will be reviewed as part of normal practice, the European Commissions recast and public consultation exercise and the current overarching review of the New Approach Directives are already underway and will ensure a review within 3 years

Ministerial Sign-off For final stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn Primarolo .....Date: ***12th November 2008***

Summary: Analysis & Evidence

Policy Option: : 3	Description: : Implement the Directive by an amendment to the Medical Devices regulation 2002-Manufacturers

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' The additional costs should be worth it for manufacturers in the long term ,as it should lead to greater clarity in the way the directive works and uniform applications across the UK.
£ 977200	
Average Annual Cost (excluding one-off)	
£ 410000	**Total Cost** (PV) **£ 1,387,200**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups' The benefits for manufacturers will be the ability for them to continue to trade within the community as their counterparts within the union.
£ N/A	
Average Annual Benefit (excluding one-off)	
£ N/A	**Total Benefit** (PV) **£ N/A**

Other **key non-monetised benefits** by 'main affected groups'

See above .Information was requested on these benefits in the consultation exercise, no response was received but avoiding enforcement action by complying ensures the manufacturers benefit from access to a £7.2b UK market. The benefits themselves are not quantifiable.

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				21/03/2010	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ NIL	
Does enforcement comply with Hampton principles?				YES	
Will implementation go beyond minimum EU requirements?				NO	
What is the value of the proposed offsetting measure per year?				£	
What is the value of changes in greenhouse gas emissions?				£ NIL	
Will the proposal have a significant impact on competition?				NO	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	N/A	N/A	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ No data Decrease of £ No Data **Net Impact** **£** No data

Key: **Annual costs and benefits:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 3	Description: : Implement the Directive by an amendment to the Medical Devices regulation 2002 - Notified Bodies

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups' By amending the Regulations we are ensuring that the UK complies with its obligation under Community law. It will also lead to greater clarity in the way the Directive works and that Notified Bodies are able to operate in a regulatory enviroment on par with their competitors in the Member States.
One-off (Transition) **Yrs**	
£ NIL	
Average Annual Cost (excluding one-off)	
£ NIL	**Total Cost** (PV) **£ NIL**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	
£ NIL	
Average Annual Benefit (excluding one-off)	
£ NIL	**Total Benefit** (PV) **£ NIL**

Other **key non-monetised benefits** by 'main affected groups'

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ N/A**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				21/03/2010	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ NIL	
Does enforcement comply with Hampton principles?				YES	
Will implementation go beyond minimum EU requirements?				NO	
What is the value of the proposed offsetting measure per year?				£ NIL	
What is the value of changes in greenhouse gas emissions?				£ NIL	
Will the proposal have a significant impact on competition?				NO	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	N/A	N/A	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits:** **(Net) Present**

Summary: Analysis & Evidence

Policy Option: 3	Description: : Implement the Directive by an amendment to the Medical Devices regulation 2002 -The Agency

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' By amending the Regulations we are ensuring that the UK complies with its obligation under Community law. It would also mean the UK would not be subject to infraction proceedings by the Commission or by individual manufacturers who may well have felt disadvantaged in some way by non-implementation by the UK.
£ NIL	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ NIL**
£ NIL	

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups'
£ NIL	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ NIL**
£ NIL	

Other **key non-monetised benefits** by 'main affected groups'

The implementation will enable us to continue to engage with our European partners in the area of medical devices on a level basis and to carry on with the co-operation through COEN to monitor medical devices throughout Europe with Public Safety at the forefront at all times.

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) £	**NET BENEFIT** (NPV Best estimate) £

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				21/03/2010	
Which organisation(s) will enforce the policy?				MHRA	
What is the total annual cost of enforcement for these organisations?				£ NIL	
Does enforcement comply with Hampton principles?				YES	
Will implementation go beyond minimum EU requirements?				NO	
What is the value of the proposed offsetting measure per year?				£	
What is the value of changes in greenhouse gas emissions?				£ NIL	
Will the proposal have a significant impact on competition?				NO	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	N/A	N/A	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ Decrease of £ **Net Impact** £

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

1. Purpose and Intended Effect of Measure

(i) Objective

The current regulatory framework for medical devices has been in operation since 1998. Whilst it has operated satisfactorily the Commission proposed a number of regulatory changes, in the light of experience, to strengthen the regime and improve implementation to continue to safeguard public health and to maintain public trust and confidence in the regulatory framework. The main objective of the amendments to the Directives are to better specify the obligations of manufacturers, notified bodies and authorities with particular respect to the key issues of conformity assessment, clinical evaluation and post market surveillance, in order to continue to ensure the highest level of safety, to ensure access to the market and to allow for a smooth functioning of the legal framework. Additionally, a legal amendment was needed to allow for more openness and transparency towards the general public and for clarifying to what extent specific products fall in the scope of the legislation. The Directive also creates a basis for the Community to participate in global activities on regulatory convergence, as they exist in the form of the Global Harmonisation Task Force for Medical Devices, GHTF, in order to ensure that Europe's position and regulatory framework is fully taken into consideration. Finally the Directive makes consequential amendments to the Active Implantable Medical Devices Directive to bring it into line with the Medical Devices Directive. There is also a small amendment to the Biocides Directive to exclude In Vitro Diagnostic Medical because f an oversight during the negotiations of the IVD Directive. The Directive does not make any consequential amendments to the Invitro Diagnostic Directive

(ii) Proposal

The proposal therefore amends existing directives in a way that clarifies existing requirements to ensure better implementation across the Community. This will bring clarity to industry, the regulators and public health benefits. Amendments cover areas such as;

- **Clinical data and evaluation**
  In order to clarify and enhance the provisions on clinical evaluation, modifications are made to a number of the Articles and to relevant Annex concerning clinical data and its evaluation and to various references to clinical data within the provisions of the Directive, including the definition of clinical data and provision for data to be included in the European databank. In addition a manufacturer will need to have in place a post market clinical follow-up as part of a post market surveillance plan.

- **Definition of Medical Device**

  The definition now states that software intended by its manufacturers to be used specifically for diagnostic and/or therapeutic purposes are now regarded as medical devices in their own right.

- **Measures to increase transparency**
  Provisions on confidentiality, which previously provided for all information obtained under the Directive as being confidential, have been relaxed, to allow certain information on all devices to be made available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices. In addition there is a provision to allow for consideration of user information being provided in electronic form.

This provision now states that the following information shall not be treated as confidential:-

(a) information on the registration of persons responsible for placing devices on the market in accordance with the Directive
(b) information to users sent out by manufacturer, authorised representative or distributor in relation to a vigilance procedure;
(c) Information contained in certificates issued, modified, supplemented, suspended or withdrawn, by Notified Bodies.

- **Legal basis for better co-ordination and communication of market surveillance activities**
  Introduces a new provision, on co-operation to provide a legal basis for co-ordination and international activities in the medical devices sector.

- **Clarification regarding medicinal products / medical device provisions**
  Devices that incorporate as an integral part a medicinal product or stable blood derivative are required to be reviewed by a Notified Body in consultation with a national authority for medicines or the European Medicines Agency (EMEA) as appropriate. These provisions which are currently contained in Annex I Section 7.4 of the Medical Devices Directive are modified to clarify both the role of the Notified Body and the relevant authority.

- **Classification Rules**
  During negotiations the Council Working Group reached a consensus to reclassify upwards from Class IIa to Class IIb disinfectants for invasive medical devices. This will mean manufacturers having to produce a design dossier for verification by their Notified Body. Stand alone software is considered to be an active medical device. All surgically invasive devices intended for transient use are in class IIa unless they are intended for use with the central nervous system then they are class III. In addition all devices specifically for X- ray diagnostic imaging are class IIa.
- **Custom-made devices**
  Custom made device manufacturers will now be required to review and document experience gained in the post production phase and to set up a post market vigilance system of reporting to authorities, as already in place for other devices. In addition a requirement is introduced that the ‘Statement’ should be available to the named patient for whom the device has been manufactured.

- **Amendment of other Directives:**
  Modification of the Active Implantable Medical Devices Directive to bring it into line with the Medical Devices Directives. Modification of the Biocides Directive to exclude In -Vitro Diagnostic Medical Devices Directives from its scope in line with the other Medical Devices Directives.

In deciding on this revised Directive the Commission also considered different means of achieving the changes. As the Directives are already in existence two basic options were open to the Commission in order to achieve their objective. Firstly "legislative" requiring modification of current legislation or secondly "non legislative" to continue the use of existing expert groups and guidance documents to drive improvements in implementation and interpretation. The Commission chose an Amending Directive to create legal certainty.

(iii) The background

The Medical Devices Directive and the Active Implantable Medical Devices Directive define the regulatory system with which manufacturers must comply in order to first place their products on the EU market.

The Medical Devices Directives are single market measures designed to remove technical barriers to trade by harmonising safety and performance requirements for medical devices. The CE mark is applied to compliant devices and manufacturers must sign a declaration of conformity and can then market their products freely throughout the European Union without having to abide by any further national controls. The Medical Devices Directive regulates a large number of medical devices from bandages to CT scanners and x ray machines. The Active Implantable Medical Devices Directive regulates devices such as pacemakers and cochlear implants which are implanted in the body long term. The regulatory approach adopted in the Directives is one that seeks to match the level of control to the perceived risk associated with the product.

The Directives require the Competent Authority in each Member State to ensure effective implementation. In the UK, the Competent Authority (CA) is the Secretary of State for Health acting through The Medicines and Healthcare Products Regulatory Agency (MHRA). The CA's main responsibilities involve ensuring compliance with the implementing regulations, monitoring and designating notified bodies (third party independent certification organisations) who assess the conformity of certain classes of devices, authorising the use of non-CE marked medical devices on humanitarian grounds, registration of certain manufacturers, and assessing notifications for clinical investigations. The Active Implantable Medical Devices Directive came fully into force 31 December 1992 and the Medical Devices Directive came fully into force in June 1998. In 2001/02 the Commission assisted by all stakeholders reviewed the functioning of the Medical Devices Directive and published its report in June 2002. The Department worked very closely with industry as part of this process. This concluded that the Directive was working well but identified areas where the Directive needed to be clearer and where implementation could be improved.

Following agreement that a more consistent and coherent implementation of the Directive 93/42/EEC concerning medical devices was necessary, the Commission Services, national authorities, notified bodies, European standards organisations and industry, through the Commission Services' Medical Devices Expert Group, (MDEG), started a review process of the medical device directives in 2001.

Arising from this review process, a Report on the functioning of the Medical Device Directive 93/42/EEC was published in June of 2002. The conclusion of this Report was that whilst the Medical Devices Directives provide in themselves an appropriate legal framework, there was room for improvement in implementation by all interested parties and that further action was needed

- to improve the level and consistency of Notified Body performance;
- to improve the National Authorities and manufacturers post market surveillance activities;
- to produce guidance on manufacturers responsibilities to have good clinical/performance data to substantiate their claims for their devices;
- to increase the level of transparency about the operation of the Directives and to put more information about devices into the public domain;
- to examine the possibility of re-classification of certain types of devices

The Commission undertook a short public consultation on its proposal in May 2005 and published the results on its website. In brief the majority of comments related to editorial changes to clarify the text. A number of issues surrounding classification were raised but the only substantive change in the final text relates to disinfectants for use with invasive devices. Two comments related to new elements –not included in the original text. A call for re-processors of single use devices to come within the scope of the Directive. The Commission acknowledged that this was an important but difficult area that they would need to revisit so did not include it in the final revision text. On custom made devices calls for third party assessment were rejected by the Commission on the grounds of simplification so instead they introduced new measures to ensure more evidence of compliance.

On 22nd December 2005 the European Commission adopted a proposal to amend two of the three main Medical Devices Directives and to make a consequential amendment to the Biocides Directive. The proposal aims to amend the exiting Directives in line with these aims. Additionally, the proposed text addressed issues around the regulation of medical devices with human tissue engineered product which acts ancillary to the medical device to complement the separate proposal (the Advanced Therapy Regulation).

Negotiations on the proposed Directive began in the Council of Minister's Working Group in January 2006 under the Austrian Presidency and continued under the Finnish Presidency and concluded during the German Presidency. In total there were twenty council meetings. The Directive was agreed at the General Affairs and External Relations Council on 23rd July 2007 and published in the Official Journal of the European Communities on 21st September 2007. Member States have until 21st December 2008 to publish and adapt the implementing legislation and shall apply the measures fully from 21st March 2010.

(iii) Rationale for Government intervention

This is a Commission led initiative which had the support of Member States including the UK. Member States, Industry, and other key stakeholders believe that more consistent and coherent implementation of the Directives concerning medical devices is necessary in order to continue the high level of public health protection. The UK has supported the initiative from the beginning and in fact was instrumental in widening the scope of the initial review and would fail to meet its obligations under EU law if we did not continue to engage in the process.

This is particularly the case as far as the amendments to the clinical investigation provision are concerned as they provide greater clarity to the regulator, industry and notified body as to when clinical data is requires to support the conformity assessment process and in what format that data is to be provided

2. Consultation

(i) Within Government

At the beginning of the review the then Medical Devices Agency (MDA) (which is now part of MHRA) set up a cross Government Steering Group comprising representatives from Department of Trade and Industry (DTI), Department of Health (DOH) and with the Devolved Administrations being kept informed. This Group met during the development of the proposal to influence the UK negotiating position and during the regulatory process itself.

(ii) Public Consultation

Again, at the beginning of the review process the then MDA set up a Stakeholders Group to meet and discuss the proposal as it has developed. In addition, the current final proposal and RIA were posted on MHRA's website **in** March 2006 inviting comment which will help develop impact thinking. To date the Agency has received no comments. Since the commencement of the review discussions have also been on an ongoing basis with external stakeholders. A meeting on the draft Impact Assessment was held on 29th November 2007 which considered those areas where there could be an impact to industry. A meeting with the relevant stakeholders on the implications of the changes for custom-made manufacturers took place on the 18th February 2008. Before and during the 12-week Public Consultation period a number of visits were undertaken to a cross section of manufacturers of custom-made devices to discuss the changes to the regulations and the cost implications for those manufacturers. The discussions, which took place on these visits, were beneficial in that the cost implications were nil because these manufacturers are already practising theses changes due to the quality systems they already have in place.

An Active Implantable manufacturer was also contacted, as the only manufacturer in the UK of AIMD's. They do not envisage any additional costs as they are already following the amendments as part of their quality system.

In addition to this, a small working group was set up consisting of DOH, Industry and MHRA representatives to gain some more information regarding costs. It was agreed the industry representative would contact the groups affected in the form of a questionnaire to try to gain as much information as possible. The questionnaire was agreed by all of those on the group and was sent out. Fourteen responses were received and the results have been incorporated into the analysis and benefits section of this RIA.

3. Costs and Benefits

(i) Sectors and groups affected

a) The medical devices sector in the UK

In 2006 the UK sector comprised around 1500 enterprises manufacturing medical and surgical equipment and orthopaedic appliances of which around 70% were small or medium sized enterprises.2006 figures are not available for the number of enterprises manufacturing in vitro diagnostics, dental gels, dressings and invalid carriages but the report produced by Arthur Little for DTI in November 2004 assessed the overall number of companies in the industry then as 1900 so it is by far the largest product area. The same report also indicated that the orthopaedics and advanced wound management were the fastest growing fields within the UK sector with the latter representing 13% of the global market at that time. R & D expenditure by a sample basket of UK companies rose by about 15% from 2004 to around £150m in 2006.Manufacturers in the sector employed around 33,000 people in 2006 (excluding single operators) and overall turnover (excluding VAT) was about £4.3b. Profits from the sale of medical devices doubled in 2006 on the previous year to about £860m and

there was also a positive trade balance on exports of about £350m. The overall size of the UK market for medical devices (excluding in vitro diagnostic devices, which are not covered by these regulatory changes) is valued in excess of 7.2b.

*2006 figures extracted from the BERR Medica; Technology Metrics report June 2008.

b) The Active Implantable Medical Devices Sector in the UK

From the information available to us we believe that there is only one manufacturer of active implantable medical devices based in the UK. The manufacturer makes neurostimulators. In addition we are aware of only one UK based Authorised Representative for a manufacturer of drug pumps. The affect of the changes to the AIMD as far as UK industry is concerned seems to be negligible as far as meeting UK National regulatory requirements.

(ii) Costs and Benefits of Option 1: Do Nothing

Option 1 would incur no costs to medical device manufacturers or to Notified Bodies if they simply placed their products on the UK market. We do not know precisely what costs could stem from infraction proceedings by the Commission, but the possibility of such proceedings and the consequences that this could entail, means that implementation of the Directive as provided by option 3 is the most appropriate means of ensuring compliance with Community law as well as helping to ensure increased levels of safety in the use of such devices. In addition manufacturers would have to meet additional regulatory costs if they wished to place their devices on the market of another EU Member State,

(iii) Costs and Benefits of Option 2: Introduction of voluntary arrangements and guidance

The regulation of medical devices in the UK is subject to the provisions of the Medical Devices Regulations 2002. An amendment to the Regulation is therefore needed to implement the Directive. Voluntary arrangements and guidance would not be sufficient. Furthermore, although we do not have precise estimates, we have no information as to whether manufacturers would sign up to voluntary arrangements or comply with guidance. This option would in any event clearly generate a cost to manufacturers. What we are not able to quantify is what additional costs may be incurred by manufacturers if there is not a uniform application of the provisions across all Member States.

(iv) Costs and Benefits of Option 3: Implement the Directive by an amendment to the Medical Devices Regulation 2002.

By amending the Regulations we are ensuring that the UK complies with its obligation under Community law. It would also mean that the UK would not be subject to infraction proceedings by the Commission or by individual manufacturers a UK notified bodies who may well have felt disadvantaged in some way by non-implementation by the UK.

Costs and Benefits of Option 3: Implement changes to the Medical Devices Directive (93/94)

(a) Manufacturers of medical devices and custom made devices and sterilisers

It is envisaged that the following changes to the Directives will incur an impact

1. Inclusion of software in the definition of a medical device. This will bring some new products within the scope of the Directive and manufacturers will need to undertake the necessary conformity assessment. **(Article 2.1. (a)(i))**

2. Devices intended to be used in accordance with both the provision of the MDD and the Personal Protective Equipment will now have to meet the health and safety requirements of both Directives. In the past they were within either one regulatory regime or the other so now there could be an additional regulatory burden on manufacturers of say for example mouthguards for both medical and sporting use. **(Article 2.1. (f))** The European Commission is drafting guidance on this point.

3. Where relevant hazards exist, devices which are also machinery should also meet the requirements of the Machinery Directive where its health and safety requirements are more specific than those listed in Annex I of the MDD. The impact of this on manufacturers needs to be properly assessed. **(Article 2.2.)** The European Commission is drafting guidance on this point.

4. For custom-made devices the manufacturer must undertake to review and document experience gained in the post-production phase and to apply any corrective action and report incidents to the Competent Authority. **(Annex II section 8. (g)).**

5. Manufacturers should now also pay special attention to any carcinogenic, mutagenic or toxic to reproduction nature of any substances contained in a device. If such devices are intended to administer and/or remove medicines, body fluids or other substances from the body or devices used to transport and store such substances contain Phthalates then devices must be labelled accordingly. If such devices intended use includes treatment of children or treatment of pregnant or nursing women the manufacturer must provide a justification for the use of these substances within the technical documentation and the instructions for use on the residual risk**.(Annex II.1.(e)**

6. If a device is for single use, the manufacturer must be able to provide information,if requested by the user, on known risk factors if the device is re-used. **Annex II.1. (j).**

7. In the statement provided by the manufacturer on a clinical investigation they must now provide a clinical investigation plan, the investigators brochure, confirmation of insurance, documents used to obtain consent, and statements indicating whether the device incorporates human blood derivatives or animal material. **(Annex II. 8. (c)).**

8. Manufacturers must undertake a clinical evaluation in order to demonstrate conformity with the applicable essential requirements in accordance with Annex X. **(Annex II. 1. (b)).**

9. A clinical investigation on the specific product should be conducted by the manufacturer of implantable devices and Class III devices unless it is duly justified to rely on existing data. **(Annex II.10. (b)).**

10. All serious adverse events in the course of a clinical investigation must be fully recorded and immediately notified to all Member States where the trial is taking place**. (Annex II.10. (d)).**

11. Class IIa surgically invasive devices have been reclassified to Class III where they are intended specifically for use in direct contact with the central nervous system. Manufacturers of these types of products will need to have them reassessed by notified bodies according to the conformity assessment procedures for Class III devices. **(Annex II 9. (c)(ii)).**

12. Devices intended for disinfecting invasive medical devices have been reclassified from Class IIa to Class IIb **(AnnexII.9. (c)(vi)).**

13. All devices intended for recording X-ray images will now be Class IIa whether they are active or not**. (Annex II.9(c) (vii)).**

14. The manufacturer in meeting the essential requirements must where appropriate provide the results of biophysical or modelling research whose validity has been demonstrated beforehand. **(Article II.1. (c)(ii)).**

It is anticipated that the following changes to the Directive will not incur any additional impacts.

1. The requirements of Article 12 which previously applied to systems and procedures packs shall now also apply to sterilisers. **(Article 2.10. (a)).**

2. Manufacturers based outside the EC should now appoint a single authorised representative to cover a range of devices or product type. **(Article 2.13. (b)).**

3. The statement of conformity provided with a custom made device shall now be available to the particular named patient. **(Article 2.3.) (AnnexII 8. (d)).** The technical document should also include details if there is more than one manufacturer's site.

4. Manufacturers must keep technical documentation on implantable devices available for national authorities for a period of 15 years as opposed to 5 years for other products, after the last product is manufactured. **(Annex II.2. (g). (i)).**

5. The manufacturer should clearly identify the product name, product code or other unambiguous reference on the declaration of conformity. **(Annex II.5. (a)).**

6. Manufacturers are required to notify Competent Authorities of the end of a clinical trial or its early termination, with justification and reasons. In the event of early termination of the clinical investigation on safety reasons this notification must also be sent to all Member States and the Commission**. (Article 16. (b)).**

7. If a device intended for clinical evaluation contains human blood derivatives or animal material the manufacturer must keep available for the Competent Authority data on tests conducted to assess safety, quality and usefulness of the substance or the risk management measures applied to reduce the risk of infection from the animal material respectively. **(Annex II .8. (e)).**

8. The clinical evaluation and its outcome plus information from post market surveillance should be included by the manufacturer in technical documentation to demonstrate conformity with the essential requirements. **(Annex II.10. (b)).**

9. Where demonstration of conformity with the essential requirements based on clinical data is not deemed to be appropriate justification must be given based on risk assessment. **(Annex II.10. (b)).**

10. Standalone software is an active medical device. **(Annex II.9. (a)(i)).**

The costs to manufacturers which have been notified to us by stakeholders amount to around £1.39m, the majority of which comprises one off transitional costs of £977k. The ongoing annual cost to industry is only £410k pa at current prices. This can be broken down as follows:-

	One off transition cost (£k)	Annual ongoing cost (£k)
Scope and device classification changes to reflect technological advancement	**278**	**110**
Tightening of controls on clinical trials	**281**	**290**
Measures to address microbiological and environmental risks	**418**	**10**

Active Implantable Medical Devices

1. The only additional change to apply to those of general medical devices is that manufacturers of AIMD's now have to register with the relevant member state. **(Article 11)**
From the information available to us we believe that there is only one manufacturer based in the UK and the affect of the changes to the AIMD as far as UK industry is concerned seems to be negligible.

(b) Notified Bodies Costs

It is anticipated that the Following changes will not incur an impact

1. Notified Bodies are obliged to inform its Competent Authority of all certificates issued, modified, supplemented, suspended, withdrawn or refused whereas in the past they only had to inform CA's about those which were withdrawn or suspended. **(Article 2 .17. (c)).**

2. Notified Bodies must now also inform all other Notified Bodies of certificates suspended, withdrawn or refused and on request certificates issued**.(Article 2.17.(c)).**

3. For Class IIa devices a Notified Body will now assess the technical documentation for one product from each device sub-category. **(Annex II.2. (h)(i)).**

4. For Class IIb devices a Notified Body will now assess the technical documentation for one product from each generic device group **(Annex II.2. (h)(i)).**

5. The notified body will now consider previous assessments (with regard to physical, chemical or biological properties) in the selection of Class IIa and b devices for assessment and keep a rationale for the samples taken available for the Competent Authority **(Annex II.2. (h)(i)).**

6. Notified bodies may issue certification to all the conformity assessment annexes for a further period of a maximum of five years on agreement with the manufacturer. **(Article 2. 9. (b)).**

7. Notified Body intervention shall be limited to the obtaining of sterility until the sterile package is opened or damaged. **(Article2.10. (**

Agency Costs

It is anticipated that the following changes will not incur an impact

1. Member States are no longer required to keep registration information, vigilance reports and notified body certification details confidential. Systems will need to be put in place to release information as required **(Article 2.20).**

2. Member States will need to have systems in place to deal with the registration of manufacturers of active implantable devices **(Article 1.11).**

3.Additional requirements on manufacturers to meet certain aspects of the PPE and Machinery Directive. MHRA to review if guidance is needed **(Article 2.1 (f) & Article 3).**

4. A new European databank will be set up by the commission to collect regulatory data on active implantable devices and the existing Eudamed data bank on general medical devices expanded to collect data on clinical trials **(Article 1. 11) (Article 2.14. (a)).**

4. Member States are now obliged to inform other Member States where a clinical trial is refused or halted. Procedures will need to be set up to do this **(Article 1.10 (c)).**

5. Member States will need to have procedures in place to receive and assess notifications of the end or early termination of clinical evaluations and adverse incidents occurring during the course of a trial. **(Article 1. 10 (d)).**

6. Member States will need to have in place more procedures to deal with notification of clinical trials and custom made device vigilance reports **(Annex II .10. (d) & Annex II.8 (g)).**

4. Consultation with Small Business: The Small Firms' Impact Test

4.1 Whilst around 70% of the medical devices sectors are small firms, the impact of the proposed changes should be minimal. The revisions exercise is in the main housekeeping, but some proposals will impact on SMEs.

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- Reclassification of disinfectants for invasive devices will necessitate an additional assessment by a Notified Body. However, it is envisaged that this additional cost will be minimal.

- New clinical data requirements may well result in the need for more clinical trials to be undertaken.

- The new custom made requirements that the statement is available to the patient should not lead to any additional costs for the manufacturer of a custom made device. The new requirement for the custom made manufacturer to introduce a system of post market assessment of the reports of vigilance for a custom made device based on the visits undertaken appear to have no or minimal impact as this appears to be part of everyday procedures within this industry.

5. Competition Assessment

5.1 The Cabinet Office's competition filter test has been applied to determine whether a simple or more detailed competition assessment is required. A simple assessment is required on the basis that the sector is not dominated by a single or small number of companies and the proposals (as currently drafted) would not lead to higher set up or ongoing costs for new or potential businesses that existing businesses would not have to meet.

6. Costs and Benefits of Option 3: Implement changes to the Active Implantable Medical Devices Directive

a) Manufacturers
b) Notified Bodies
c) The Agency

6.1 All the changes made to the MDD apply to the AIMD and have been incorporated into the RIA for the MDD. With the exception of the following additions which are specific to the AIMD

6.2. Manufacturers of AIMD are now required to register with Competent Authorities wherever their device is put on the market or put into service **(Article 1.11)**.

6.3.Regulatory data shall be stored on a European Databank accessible to Competent Authorities. This will involve MHRA passing on data relating to notified body certificates issued or changed vigilance and clinical investigations in a standard format **(Article 1.11)**.

(iii) Consultation with Small Business: The Small Firms Impact Test

Companies manufacturing AIMD's are in the main well established national or multinational companies. For these reasons the Small Business Section are content that a small firm's impact test is not needed.

7. Competition Assessment

7.1. Although the regulation will slightly increase requirements for entry to this market they are mainly housekeeping measures and the cost is low in comparison to production. Given the small number of companies involved, the specialist nature of the market and the fact that the changes are likely to apply equally to all companies and products there is unlikely to be any impact on competition.

8. Issues of Fairness and Equity

8.1. The proposals covered in this RIA have been considered in accordance with the duties contained in the Race Relations (Amendment) Act 2000. It is not anticipated that they will have any discriminatory or adverse effects on minority ethnic communities, disability groups or voluntary sectors. However during the period of the regulations being laid before parliament (7th November 2008) and the Regulations coming into force (21st March 2010) we will be undertaking a mini consultation exercise in conjunction with the BDA and DOH regarding the changes to Custom Made Statements and how best to implement .This was identified from the equality screening assessment (Annex E) which was carried out. The other amendments to the regulations will not affect anyone other than manufacturers and

stakeholders and full consultation with these groups has taken place from the outset of the negotiations in Europe to the present

9. Enforcement and Sanctions

9.1. The Medicines and Healthcare Products Regulatory Agency currently enforce the Medical Devices Directives and the proposed changes will not affect their current activity or impose any additional statutory burdens upon their activities.

10. Monitoring and Review

10.1. The proposed amendment Directive does not incorporate a revision provision but the implementing Regulations will be reviewed as part of normal practice. In addition, the Commission's recast exercise and the current review of the New Approach will require a review of the workings of the Directives.

11. Summary and Recommendations

11.1. Option 3 best meets the objectives of transpositioning the Revision Directive. This will lead to a consistent approach as a single market measure that will benefit the UK medical devices industry. This will also enable the UK to meet its European obligations in terms of transposition of the Directive.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	N/A	N/A
Sustainable Development	N/A	N/A
Carbon Assessment	N/A	N/A
Other Environment	N/A	N/A
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	N/A	N/A

Annexes

Annex A

As briefly outlined in the summary base, the implementation of these amendments to the regulations have involved numerous and different types of consultations with our stakeholders. Regular meetings were held with industry during the initial review undertaken by the European Commission and negotiating process. Comments were also invited from stakeholders through the MHRA website during the whole of this process. No comments were received during this period and we believe this was due to the success of the stakeholder group and the involvement of them and their views during the negotiating process.

Additional meetings were held in the run up to and during the 12 week consultation process on the Transposition Package. This consisted of Policy staff from MHRA visiting a number of manufacturers. Our stakeholder representatives had sent out invitations to manufacturers to invite MHRA staff to visit them and gain their opinions on the amendments and subsequent changes to the way they conduct their business. This was an extremely helpful exercise and our visits allowed us to talk to small and medium manufacturers in different custom made devices areas. Five different types of manufacturer were visited and the devices, which they manufacture, include artificial eyes, maxillofacial medical devices, custom-made orthoses and custom-made dental devices such as bridge and crowns.

The visits allowed us to look closely at the processes and quality systems in place. All of the businesses visited were certain that there would be a nil cost impact as the use of their quality systems already ensured that the amendments to the directives would be covered by their present practices.

In addition to this, 48 Public Consultation Packages were sent out to various organisations (Annex D) that will have had interest in the amendments. Specific contact was made with the only manufacturer of Active Implantable Devices in the UK who confirmed our initial view that the proposed changes to the Active Implantable Directive would have no costs as he manufactured within these provisions already.

Our public consultation documents were also posted onto the MHRA website and comments were invited. During the 12-week consultation period, we received comments from four stakeholders (Annex C) which have been collated and responded to.

In addition to this on the advice of the Government Economist, a small working group was set up to gain more information on the possible impact to industry. A questionnaire was devised by the stakeholder representative on the group (Annex B) and agreed by the other representatives. This was then sent out to industry for them to complete. We have received 12 responses. The costing from these questionnaires has been used to complete the analysis and evidence for the RIA.

An e-mail was also sent to all of the notified bodies reminding them of the consultation period and the need for us to be made aware of any costs, which they may incur due to the changes to the Directive. As of the deadline, there was one response which indicated there would be no additional costs incurred.

The costing for option 1 was non-applicable as both industry and notified bodies would not benefit from this option, manufacturers would be disadvantaged due to the procedures not being uniformed throughout the European Community and manufacturers may use notified bodies elsewhere in the community thus disadvantaging the notified bodies based in the UK. For the UK not to implement would be a breach of it's obligations under European Law and would result in infraction proceedings, it was impossible to cost for this since there have been no instances of any government departments going with a 'Do Nothing' option.

The 2nd option, which the agency considered, was that of the introduction of voluntary arrangements for manufacturers, notified bodies and the agency. However this option would pose a number of problems being this would not constitute adequate implementation of the Commission Directive, different requirements being imposed on manufacturers by different member states which would add a financial burden to manufacturers, it would be likely that notified bodies would be used in the community instead of the UK and finally the chances of infraction proceedings being taken against the UK would still be present. This was again impossible to cost, as the consultations with stakeholders was unable to provide us with any figures in this area.

Option 3 is to implement the directive into UK legislation. As a member of the European Community, the negotiating process for these amendments and the involvement of stakeholders with the agency throughout the process enabled the UK to ensure the negotiations have little or no ill effect on any of the parties in the UK who will be involved

in the changes. No changes are proposed over and above those contained in the Amendment Directive and the minimum possible implementation is being transposed. As such, this option is considered by the Agency to be the best for those likely to be affected. The costing for this option was calculated from the return of questionnaires, which were sent out to stakeholders and visits undertaken by the agency to individual manufacturers. As detailed in paragraph four of the main Impact Assessment the cost is minimal (£1.4m) and this is reflected in the analysis and evidence pages for this option.

Most of the changes implement current practice and do not incur costs. Any additional costs incurred are minimal and offset by the benefits of improvements in clarity, public safety and a level playing field for access to EU markets. Additional information was requested in the consultation letter about monetarising these benefits but no data was forthcoming. We take it from this that types of benefits involved are unquantifiable.

Few if any of the changes affect manufacturing practices and would not therefore have a significant effect on green house gas emissions.

Consideration has also been given to any possible impact on equality. The measures proposed affect the medical devices industry generally and contain no specific impact on race, gender or disability.

Annex B

MHRA Regulatory Impact Assessment concerning Implementation of The Medical Devices (Amendment) Regulations 2008

References given in the text below relate to Council Directive 2007/47/EC.

To see how 2007/47/EC fits into 93/42/EC a consolidated version of the text is available.

Other documents referenced are:
Personal Protective Equipment Directive
Machinery Directive

Please Note:

1. **Underlined text denotes links to other documents that may provide information that is useful for completing this questionnaire.**
2. **Please answer all questions in the Affected? Yes/No column – negative information is important in terms of this exercise**
3. **If costs associated with a particular measure are minimal, please state this rather than leaving a blank.**
4. **Information provided will be treated in the strictest confidence and will be seen only by SDMA and ABHI staff.**

Name	Company	E-mail	Phone

Issue	Affected? Yes/No	Cost (one off) £000	Cost (annual) £000
Inclusion of software in the definition of a medical device. This will bring some new products within the scope of the directive and manufacturers will need to undertake the necessary conformity assessment. (Article 2.1 (a)(i)). Devices that monitor patients or control therapy are frequently and increasingly driven by 'medical software'. Where functionality derives primarily from the medical software, that software can be construed to be a medical device. Examples of where this may be the case include: Monitors: heart rate, blood pressure, breathing rate, use software to interpret the sensor information and display it in a meaningful way on a			

Issue	Affected? Yes/No	Cost (one off) £000	Cost (annual) £000
monitor. Medication pumps: These devices are programmed to pump a certain amount of plasma, blood, saline solution, or medication into a patient at a certain rate. The software provides the ability to control many aspects of treatment procedures. Analysis: Many devices, such as CAT scanners, measure raw data that is essentially meaningless to people. Software reinterprets this data to create images that doctors can read and understand. Expert Systems: A variety of expert systems have been created to indicate what care pathways could be followed. Therapy delivery: The software in implantable pacemakers and defibrillators provides fault-tolerant, real-time, mission-critical monitoring of cardiac rhythms and associated therapy delivery. Medical and healthcare educational software: Software used as an educational or study tool for healthcare professionals.			
Devices intended to be used in accordance with both the provision of the MDD and the Personal Protective Equipment Directive will now have to meet the health and safety requirements of both Directives. In the past they were within either one regulatory regime or the other so now, there could be an additional regulatory burden on manufacturers of, for example mouthguards for both medical and sporting use. (Article 2.1 (f)). The Commission has prepared an interpretative document on the relationship between the Personal Protective Equipment Directive and the MDD.			
Where relevant hazards exist, devices, which are also machinery, should also meet the requirements of the Machinery Directive where its health and safety requirements are more specific than those listed in Annex I of the MDD. The impact of this on manufacturers needs to be properly assessed (Article 2.2). Examples of medical devices that are also machinery are:			

Issue	Affected? Yes/No	Cost (one off) £000	Cost (annual) £000
Mobility and moving and handling devices, e.g. hoists, profiling beds, powered wheelchairs, riser recliner chairs; Powered surgical instruments, e.g. saws, drills; Devices with powered movement, e.g. X-ray machines, powered operating tables, MRI scanners; Devices with external moving parts, e.g. infusion pumps, dialysis machines, ventilators; Devices with internal moving parts, e.g. endoscopes with light sources, blood gas analysers. The Commission has prepared an interpretative document on the relationship between the Machinery Directive and the MDD. In addition, COCIR has prepared a document identifying those Essential Requirements of the Machinery Directive that are either not met by or are in conflict with requirements under the MDD (please note that this is for guidance only, companies should address these points with their notified body).  MDD & Machinery Directive Essential Re			
Manufacturers should now pay special attention to the presence in a medical device of any substances that are carcinogenic, mutagenic or toxic to reproduction. If such devices are intended to administer and/or remove medicines, body fluids or other substances from the body or if they are used to transport and store such substances, and if they contain phthalates then they must be labelled accordingly. If such devices' intended use includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a justification for the use of these substances within the technical documentation and information on the residual risk in the instructions for use. (Annex II, 1. (e)). A list of substances carcinogenic, mutagenic or toxic to reproduction is contained in Annex 1 of Directive 67/548/EEC.			

Issue	Affected? Yes/No	Cost (one off) £000	Cost (annual) £000
If a device is for single use, the manufacturer must be able to provide information, if requested by the users, on known risk factors if the device is reused. (Annex II, 1. (j)).			
Clinical Investigations			
In the statement provided by the manufacturer on a clinical investigation they must now provide a clinical investigation plan, the investigators' brochure, confirmation of insurance, documents used to obtain consent, and statements indicating whether the device incorporates human blood derivatives or animal material (Annex II, 8.(c)). MHRA has produced guidance for manufacturers on clinical investigations to be carried out in the UK.			
Manufacturers must undertake a clinical evaluation in order to demonstrate conformity with the applicable essential requirements in accordance with Annex X. (Annex II, 1.(b)). Manufacturers should note the difference between a clinical evaluation and a clinical investigation. Where a clinical evaluation establishes that sufficient information already exists to demonstrate conformity with the essential requirements then a clinical investigation need not be carried out. Such information can take the form of data held by the company, data from literature search, etc.			
A clinical investigation on the specific product should be conducted by the manufacturer of implantable devices and Class III devices unless it is duly justified to rely on existing data. (Annex II, 10.(b)).			
All serious adverse events in the course of a clinical investigation must be fully recorded and immediately notified to all Member States where the trial is taking place. (Annex II, 10.(d)).			
Class IIa surgically invasive devices have			

Issue	Affected? Yes/No	Cost (one off) £000	Cost (annual) £000
been reclassified to Class III where they are intended specifically for use in direct contact with the central nervous system. Manufacturers of these types of products will need to have them reassessed by notified bodies according to the conformity assessment procedures for Class III devices. (Annex II, 9.(c)(ii)). Manufacturers should note that this requirement *does not apply* to surgically invasive devices intended for general purposes but *which may be used* in direct contact with the central nervous system.			
Devices intended for disinfecting invasive medical devices have been classified from Class IIa to Class IIb. (Annex II, 9.(c)(vi)).			
All devices intended for recording X-ray images will now be Class IIa whether they are active or not. (Annex II, 9.(c)(vii)).			
The manufacturer in meeting the essential requirements must, where appropriate, provide the results of biophysical or modelling research whose validity has been demonstrated beforehand. (Annex II, 1.(c)(ii)). A brief overview of biophysics can be found on the Biophysical Society's website.			

Other Changes

It is anticipated that the following changes to the directive will only have minimal impacts. If you believe there will be a substantial impact, please indicate this in the space provided and if possible estimate any associated costs.

Issue	Comments
The requirements of Article 12 which previously applied to systems and procedure packs shall now also apply to sterilisers. (Article 2.10. (a)).	
Manufacturers based outside the EC should now appoint a single authorised representative to cover a range of devices or product type. (Article 2.13. (b)).	
The statement of conformity provided with a custom made device shall now be available to the particular named patient. (Article 2.3) (Annex II, 8.(d)). The technical document should also include details if there is more than one manufacturer's site.	
Manufacturers must keep technical documentation on implantable devices available for national authorities for a period of 15 years as opposed to 5 years for other products, after the last product is manufactured. (Annex II, 2.(g)(i)).	
The manufacturer should clearly identify the product name, product code or other unambiguous reference on the declaration of conformity. (Annex II, 5(a)).	
Manufacturers are required to notify Competent Authorities of the end of a clinical trial or its early termination, with justification and reasons. In the event of early termination of the clinical investigation on safety reasons this notification must also be sent to all Member States and the Commission. (Article 16, (b)).	

Issue	Comments
If a device intended for clinical evaluation contains human blood derivatives or animal material, the manufacturer must keep available for the Competent Authority data on tests conducted to assess safety, quality and usefulness of the substance or the risk management measures applied to reduce the risk of infection from the animal material respectively. (Annex II, 8.(e)).	
The clinical evaluation and its outcome plus information from post market surveillance should be included by the manufacturer in technical documentation to demonstrate conformity with the essential requirements. (Annex II, 10.(b)).	
Where demonstration of conformity with the essential requirements based on clinical data is not deemed to be appropriate, justification must be given based on risk assessment. (Annex II, 10.(b)).	
Standalone software is an active medical device. (Annex II, 9.(a)(i)).	

Annex C

Feedback from the Public Consultation of the Revision of the MDD.

Question/Query	Organisation	Response
	Surgical Dressings Manufacturers Association.	
Clinical Evaluation Clarification is needed as to what constitutes a clinical evaluation in the context of what the medical devices is to be used for. If requirement is for all medical devices including class I then there will be considerable increase of costs to manufacturers. If the requirement remains the same i.e. active implantable and class III devices then there will be no significant cost. The impact of this will depend upon the device and its 'intended purpose'. We would seek clarification as to which medical devices this applies to e.g. Class I or all medical devices		**Clinical Evaluation** The requirement is now that manufacturers must undertake clinical investigations on the basis of the new provisions in the Revision Directive. What this means in practice is that manufacturers of all medical devices irrespective of Class must be able to provide clinical data of some sort to support their declaration of conformity. However this does not mean that all devices must be subject to a clinical investigation but manufacturers must be able to demonstrate conformity with data from other sources if appropriate.
Standalone Software Better definition of what is included and excluded, as software would be		**Standalone Software** The amendment itself seeks to clarify what software should be

helpful.		included in the definition of a device by adding standalone software. The Agency is working on providing guidance in this area including providing examples of what constitutes standalone software in the context of the new definition. We are also working with the European Commission to hopefully provide some European guidance.
Machinery Directive Overlap. A European consensus is needed on this question. **Technical Review of Class IIa and Class IIb devices.** BSI is concerned at the lack of transparency in how this requirement will be implemented in both terms of the number of samples taken and depth of assessment to the samples. Definitive and authoritive guidance is needed to ensure	**British Standards Institute.**	**Machinery Directive Overlap** The commission have issued an interpretation document on this issue which is on their website. We are in consultation with BERR and the HSE to see whether this guidance needs to be supplemented in some way. **Technical Review of Class IIa and Class IIb devices.** Guidance is being prepared at a European Level and should be available shortly.

sufficient resources are obtained and to ensure uniform application across the EU. **Guidance** Guidance is urgently needed on the sampling of technical documentation also on conformity assessment against Machinery Directive aspects.		**Guidance** See above.
Availability of Conformity Statement To provide a statement for the patient directly from the dental laboratory via the dentist or dental practice does not provide any practical restrictions as this process is carried out as standard with every custom made dental appliance placed on the market to a dentist or dental practice, the only anticipated difference is the issuing of two copies rather than one. It would make much sense if an agreed layout of such a statement were prepared with MHRA as guidance so patients would not be confused with different information.	**Dental Laboratory Association**	**Availability of Conformity Statement** It is agreed that making a copy of the statement available to patients would not incur a significant additional cost. Details of the information that should be provided in the statement are laid down in Annex VIII of the Medical Devices Directive. Manufacturers are free to set the format themselves according to their own circumstances e.g. printing arrangements. The Agency would be happy to discuss with the DLA the practicalities of this new requirement.

Overlap with Personal Protective Equipment Directive The MDD now states that any MD claiming protective properties must take account of the PPED. BSIF had assumed that "taking account "of all of PPED Directive and not just part of it. The product would be a medical device but it will "take account" of the PPED manifesting protective properties. The simplicity of this is that there will not be an issue regarding "dual use" products the DOH can delegate this part of enforcement to Trading Standards	**British Safety Industries Federation**	**Overlap with Personal Protective Equipment Directive.** The legal text is that in Directive 2007/47 and any such "dual" medical products placed on the market will be regulated as a medical device and come within that regulatory regime. Not all the requirements of the PPE Directive should apply to these "dual purpose" medical devices. Only the relevant parts of the basic health and safety requirements of the PPE Directive will apply not the whole of Annex II. If these devices are placed on the market as class I medical devices then the manufacturer or his authorised representative must register with the competent authority where his business is based. In the UK, this is MHRA. As well as investigating all allegations of non-compliance within the Directive, the agency also proactively investigates such manufacturers from the register.

Annex D

British Glove Association
32 Park Hill Road
Harborne
Birmingham
B17 9SL

Mr C Jepson
SGS UK Ltd
Weston Super Mare
Somerset
BS22 OWA

Mrs Penny Henderson
British Oncology
Data Managers Ass
PO Box 87
Banbridge
BT32 3YT

British Dental Association
Northern Ireland
The Mount
2 Woodstock Link
Belfast
BT6 8DD

Royal Pharmaceutical Society
Northern Ireland
73 University St
Belfast
BT7 1HL

BMA Northern Ireland
16 Cromac Place,
Cromac Wood
Ormeau Road
Belfast BT7 2JB

BMA Wales
5th Floor 2 Caspian Point
Caspian Way
Cardiff Bay
CF10 4DQ

British Dental Association
4th Floor, 2 Caspian Point
Caspian Way
Cardiff Bay
CF10 4DQ

Surgical Dressing Manufacturers Ass
70 Egremont Rd
Milnrow
Rochdale
Lancashire
OL16 4ES

BAREM
The Stables
Sugworth Lane
Radley
Abington
OX14 2HX

Wheelchair Manufacturer Ass
Spencer House
Britannia House
Banbury
Oxfordshire
OX16 8DP

Vernon Carus Ltd
1 Western Avenue
Matrix Park
Buckshaw Village
Chorley
PR7 7NB

BHAMA
C/o Knowles Electronics
73 Victoria Road
Burgess Hill
West Sussex
RH15 9LP

Association of Optometrists
61 Southwark St
London
SE1 7JN

ABHI
111 Westminster Bridge Rd
London
SE1 7HR

Mr Simon Rodwell
ACLM
PO Box 735
Devices
Wiltshire
SN10 3TQ

Mr R Hodgkinson
BHTA
1 Webbs Court
Buckhurst Avenue
Kent TN13 1LZ

Barry Hassell
Independent Healthcare Ass
Westminster Tower
3 Albert Embankment
London SE1 7SP

Mr C McKee
Mobility Products Association
80 High St
Guilden Morden
Royston
Herts SG8 OJS

Mr Kirkman
The Scottish Biomedical Ass
14/15 Belgrave Sq
London
SW1 8PS

Mr G J Carmichael
Orthodontics Tech Ass
1 Severn Hill
Fulwood
Preston
PR2 3RD

John Rowan
UK Rep to EU
10 Avenue D'Auderghem
1040 Brussels
Belgium

ABDO
Godmersham Park
Canterbury
Kent
CT4 7DT

Mr J Andrews
LRQA LTD
Hiramford
Middlemarch Office, Village
Sisken Drive
Coventry CV3 4FJ

BHTA
New Loom House
Suite 4.06, 101 Back Church Lane
London
E1 1LU

BIRA
7 Heron Quays
Marsh Wall
London
E14 4JB

OTA
British Orthodontic Society
12 Bridewell Place
London
EC4 6AP

SAMA
C/O Vernon Works
Waterford St
Basford
Nottingham
NG6 ODH

Dental Laboratories Ass
44-46 Wollaton Road
Beeston
Nottingham
NG9 2NR

Mr Austin Simmons
SATRA Quality Assurance
Rockingham Road
Kettering
Northamptonshire
NN16 9JH

Mrs C Campbell
Sterilised Suture Manufacturers
C/O Sutures
Vauxhall Industrial Estate
Ruabon Road
Clwydd LL14 6HA

Mr Ian Hunter
Association of Optometrists
Bridge House
233-234 Blackfriars Road
London
SE1 8NW

G L FRASER
Ass of X-Ray Equipment Manufacturer
Westminster Tower
3 Albert Embankment
London
SE1 7SW

Mrs M Cooper
British Dental Trade Ass
Mineral Lane
Chesham
Bucks
HP5 1NL

BMA
National BMA Offices Scotland
14 Queen St
Edinburgh
EH2 1LL

British Dental Ass Scotland
Forsyth House
Lomond Court
Castle Business Park
Stirling FK9 4TU

Federation of Small Businesses
Sir Frank Whittle Way
Blackpool Business Park
Blackpool
FY4 2FE

Mr D Harding
Sterile Barrier Association
9 Brockley Acres
Eastcombe
Stroud GL6 7DU

UL International (UK) Ltd
Wonersh House, The Guildway
Old Portsmouth Road
Guildford
GU3 1LR

The Patients Association
PO Box 935
Harrow
Middlesex
HA1 3YG

Royal College of General Practitioners
14 Princes Gate
Hyde Park
London
SW7 1PU

Ms E Deadman
MATCH
Brunel University
Uxbridge
UB8 3PH

General Dental Practitioners Ass
2nd Floor
61 Harley St
London
W1G8QU

British Dental Association
64 Wimpole St
London
W1G 8QU

Federation of Manufacturing Opticians
199 Gloucester Terrace
London
W2 6DL

BMA
Tavistock Square
London
WC1H 9JP

Association of Medical Research Charities
61 Grays Inn Road
London
WC1X 8TL

Sabine Lecrenier
Medical Devices Sector
Breydel Building
45 Avenue
D'Auderghem
Belgium

Annex E

Screening template

Title and short description

The Medical Devices Amendment Regulations 2008 will transpose EC Directive 2007/47/EC into the UK law. Directive 2007/47 in turn amends Directive 93/42 and 90/385/EEC, which relate to the placing on the market of general medical devices and active implantable medical devices. The changes, which are detailed in, paragraph three of the evidence base in the regulatory impact assessment. These changes do not introduce any basic new requirements but rather seek to clarify and refine existing provisions to ensure more consistent application across member states. The Directives lay down requirements for the safety, quality and performance of devices that manufacturers have to meet before placing them on the market. Apart from any improvement in Public Health Protection, that the changes bring most affect manufacturers and do not have a direct effect on individuals.

Negative impact

Disability
The new provision to make custom-made device statements available to the patient is the only area of possible impact on the disabled. The implications for the blind in particular will be dealt with in the mini consultation planned to take place after the regulations been laid in Parliament. The consultation will take into account the views of patient groups as well as professional organisations such as the BDA AND gdc it will be co-ordinated by the Department of Health Policy Division responsible for dental services. Any issues for the disabled will be dealt with in the administrative arrangements and guidance arising out of the consultation exercise.

Ethnicity.
As above any issue of language or communication, arising from the consultation due to ethnicity will also be addressed through the administrative arrangements and guidance before the regulations come into force in March 2010.

Gender
The new provisions being introduced impact principally on medical device manufacturers. None of the changes presents any specific barriers to, excludes individuals according to their gender, or has a negative effect on equality or community relations.

Sexual Orientation
The new provisions being introduced impact principally on medical device manufacturers. None of the changes presents any specific barriers to,

excludes individuals according to their sexual orientation, or has a negative effect on equality or community relations.
Age
The new provisions being introduced impact principally on medical device manufacturers. None of the changes presents any specific barriers to, excludes individuals according to their age, or has a negative effect on equality or community relations.

Religion or Belief
The new provisions being introduced impact principally on medical device manufacturers. None of the changes presents any specific barriers to, excludes individuals according to their religion or belief, or has a negative effect on equality or community relations.

Human Rights

None of the amendments to these regulations will affect the Human Rights Act 2000 section 6 and as such, we as a public authority are ensuring the compatibility of these regulations with convention rights.

Positive impact

Whilst none of the changes are directly aimed at promoting or protecting equality or human rights, they will bring benefits in terms of improving public health protection. Greater clarity and consistency of application will also assist the UK medical devices industry access to the EC market.

Evidence

In relation to the custom-made statement at present, we do not have any evidence, as this will be gathered during the consultation after the regulations have been laid.
For the rest of the amendments to the regulations previously detailed these changes affect manufacturers, who have been involved since the EU Commission decision to amend the regulations, their involvement and opinions were taken into account throughout the negotiating process and consultation periods.

Screen Assessment In light of the above and evidence currently available an adverse impact is unlikely. However, positive impact is also unlikely.

Next Steps

At present, a full EQIA does not appear to be necessary. However, we will be undertaking a consultation as explained in the negative impact section above. As the consultation, progresses we will use the information and views gathered to monitor the situation and make any changes as and when necessary.

Signature (Director) 

Transposition Note for Commission Directive 2007/47/EC of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

The Medical Devices (Amendment) Regulations 2008 ("the Regulations") do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Articles	Objectives	Implementation	Responsibility
Article 1	To amend Directive 90/385/EEC.	The Medical Devices (Amendment) Regulations 2008	Secretary of State
1.(a).(i)	Amends the definition of a medical device to include a new element that indicates software when designed for diagnostic and/or therapeutic purposes is a medical device in its own right.	Regulation 2 (h) amends the definition of a medical device contained in regulations 2.1 of the principal regulations	Secretary of State
1.(a)(ii)	Amends the definition of 'custom made device' to emphasise that the prescription is made out by a "duly qualified medical practitioner" for the sole use of a particular patient. Definition of 'device intended for clinical investigation' also amended to emphasis the prescription is	Regulation 6 amends the definition of custom made device contained in regulation 15 of the principal regulations Regulation 2(e) amends the definition of "intended for	Secretary of State

	by a duly qualified medical practitioner . The definition of 'intended purpose' is amended to make clear that the use for the device is based on data supplied by the manufacturer. All these changes align the definitions to those in Directive 93/42/EEC.	clinical investigation" in reg 2.1 of the Principal Regulation.	
1.(a)(iii)	Adds new definitions of 'authorised representatives' and 'clinical data' in line with those in Directive 93/42/EEC.	Regulation 2 (b) and 2(c) amend the definition of authorised representative and insert clinical data as contained in regulation 2.1 of the principal regulations	Secretary of State
1.(b)	This amends the reference to the Directives which regulate medicines.	Regulation 12 (c) insert new paragraph to amend regulation 21 of the principal regulations	Secretary of State
1.(c)	This is to clarify the borderline with medicinal products by stressing that the medicine component part acts ancillary to the device. This is in line with 93/42/EC.	Regulation 3(2) insert to amend regulation 3 of the principal regulations	Secretary of State
1.(d)	To include a	Regulation 3 (1)	Secretary of

	specific reference to medical devices containing human blood derivatives.	(3) (4) to amend regulation 3 of the principal regulations.	State
1.(e)	Applies Directive 2004/108/EEC on electromagnetic compatibility to Directive 90/385/EEC in line with 93/42/EEC.	No requirement to transpose into national legislation.	
1.(f)	To include a specific list of product areas exempt from the provisions of 90/385/ EC in line with that in 93/42/EC.	Regulation 3 amends the list of exemptions in regulation 3 of the Principal Regulations.	Secretary of State
2.	To bring Member States responsibilities with regard to ensuring only compliant products are placed on the market or put into service into line 93/42/EEC	No requirement to transpose this specific change in the implementing legislation as this underpins the whole rational of the devices regime.	
3.	A new requirement to apply the relevant health and safety requirements of the Machinery Directive 2006/42/EEC if they are not covered in 90/385/EC to those devices which also falls within the	Regulation 12 (b) introduces new regulation 21 (b) (2) into the Principal Regulations.	Secretary of State

	definition of a machine or has a machine as a component part.		
4.	To bring Member States responsibilities with regard to creating obstacles to the placing on the market or putting service into line with Directive 93/42/EEC	No requirement to transpose this specific change in the implementing legislation as this underpins the whole rational of the devices regime.	
5.	To clarify the use of harmonised standards to bring it line with Directive 93/42/EEC	No requirement to transpose into implementing legislation	
6.	To bring the Standing Committee provision into line with Decision 1999/468/EC.	No requirement to transpose into implementing legislation	
7.	To bring the Safeguard procedure into line with the new comitology procedures.	No requirement to transpose into implementing legislation	
8.	New provision to subject decisions on the means by which the information needed to use medical devices safely to be set out to determine conditions information to be publicly available is subject to the	No requirement to transpose into implementing legislation	

	new comitology procedure.		
9.	Allows Member states to submit a request to the commission subject decisions on conformity or whether a product falls within the definition of an active implantable medical device to the new comitology procedure.	No requirement to transpose into implementing legislation	
10.	This is a new provision which allows for Member States to communicate details of clinical investigations which are refused or halted or there is a significant modification or temporary interruption of the investigation. In addition a provision is added to require manufacturers to inform the authorities of the end of the trial in line with 93/42/EC.	This is a requirement on Member States not manufacturers so is not subject to be transposed into the Regulations.	
11.	This is a new provision which introduces registration with	Regulation13(3), (a), (b), (c),4 (a) and (b) and 5 to amend	Secretary of State

	Member States for Active Implantable Devices for this information to be stored in a European Databank accessible to Competent Authorities. In addition there is the inclusion of procedures for Member States to take health protection measures in line with 93/42/EC.	regulation 30 of the principal regulations. No requirement to transpose this element into implementing legislation	
12.	In order to ensure a consistent application of the criteria set out for the designation of notified bodies. Certain information will be exchanged between notified bodies and competent authorities and other member states. This is line with 93/42/EC	Regulation 15 omit in para (4) and (5) in regulation 47 of the principal regulations.	Secretary of State
13.	To ensure consistency of interpretation between member states enforcement responsibilities under directives 90/385 and directive 93/42. This includes a new	This is already covered under regulation 61 of the principal regulations	Secretary of State

	infringement of when a CE is "missing"		
14	In line with Directive 93/42 Member States shall be required to give the exact grounds on which a product has been removed from the market and to advise the party concerned for the remedies available to them under national law.	17 (a) (b) (c) amend regulation 63 of the principal regulations.	Secretary of State
15	In support of transparency in Community legislation, certain information related to medical devices and their conformity with Directive 93/42/EEC, in particular information on registration, on vigilance reports and on certificates, should be available to any interested party and the public. Also states that decisions on other information which could be made available subject to new comitology procedure.	Not being transposed already covered by Part 9 of the Enterprise Act	

16	To better coordinate the application and efficiency of national resources when applied to issues related to Directive 90/385/EEC, the Member States should cooperate with each other and at international level	This is a requirement on Member States and is not subject to transposition.	
17	This article allows amendments to be made to Annex 1-7 of Directive 90/385/EEC in line with Annex I of the Amending Directive.	The Annexes to Directive 90/385/EC as amended by 2007/47/EC are transposed by cross reference in the Principal Regulation.	Secretary of State
Article 2	**To amend Directive 93/42**		
2.1.(a)(i)	Amends the definition of a medical device to include a new element that software, when specifically for diagnostic and/or therapeutic purposes is a medical device in its own right	Regulation 2 (h) amends the definition of a medical device contained in regulations 2.1 of the principal regulations	Secretary of State
2.1(a)(ii).	Introduces new definition of clinical data	Regulation 2 (b) and 2(c) inserts new definition of clinical data as contained in	Secretary of State

		regulation 2.1 of the principal regulations	
2.1.(b)	This amends the reference to the Directives which regulate medicines	Regulation 12 (c) insert new paragraph to amend regulation 21 of the principal regulations	Secretary of State
2.1(c)	This amends the reference to the Directives which regulate medicines	Regulation 12 (c) insert new paragraph to amend regulation 21 of the principal regulations	Secretary of State
2.1.(d)	This amends the reference to the Directives which regulate medicines	Regulation 12 (c) insert new paragraph to amend regulation 21 of the principal regulations	Secretary of State
2.1. (e)	This provision amends the exclusion criteria as they relate to medicinal products and transplants and cells and tissues of human origin.	Regulation 3 amends the list of exemptions in regulation 3 of the Principal Regulations	Secretary of State
2.1. (f)	This replaces the old exclusion for products covered by the Personal protective Equipment Directive making clear the legal requirements for such dual purpose products when they are placed	Regulation 6. (c) inserts new regulation 6.(10) into the Principal Regulation.	Secretary of State

	on the market as medical devices.		
2.1. (g)	Update provisions as they relate to Euratum and Electromagnetic Compatibility.	This does not require to be transposed into implementing legislation.	
2.2.	A new requirement to apply the relevant health and safety requirements of the Machinery Directive 2006/42/EEC if they are not covered in 90/385/EC to those devices which also falls within the definition of a machine or has a machine as a component part.	Regulation 5 introduces new regulation 8 (3) into the Principal Regulations.	Secretary of State
2.3.	New requirement that the statement of conformity produced by the manufacturer shall be available to the patient.	Regulation 6 introduces new regulation 9 (6) to ensure that patient is aware of the existence of the statement of conformity. In addition regulation 8 inserts new regulation 15 (e) on this provision.	Secretary of State
2.4.	Reference to new technical standards Regulation.	No requirement to transpose this element into implementing legislation	
2.5.	Amends the Comitology provisions in line with the	No requirement to transpose this element into implementing	

	new Decision.	legislation	
2.6.	Amends the Comitology provisions in line with the new Decision.	No requirement to transpose this element into implementing legislation	
2.7	Brings classification decisions within the new comitology provisions.	No requirement to transpose this element into implementing legislation	
2.8	Brings the safeguard procedure within the new comitology provisions.	No requirement to transpose this element into implementing legislation	
2.9.	Clarifies the period of validity of EC Certificates for various conformity assessment Annexes. In addition adds that alternative methods of making information available about a device shall be subject to the new comitology procedure.	No requirement to transpose this element into implementing legislation	
2.10.	Clarifies the activities of sterilisers of systems or procedure packs.	Regulation 7 amends regulation 14 of the Principal Regulations.	Secretary of State
2.11.	This places a responsibility on the European Commission to produce a report for the Council and Parliament on reprocessing	No requirement to transpose this element into implementing legislation	

	of medical devices.		
2.12	Decisions about classification and derogation issues now subject to the new comitology procedure.	No requirement to transpose this element into implementing legislation	
2.13	Stipulates that where a manufacturer is placed outside of the EU he must designate a single authorised representative.	Regulation 2 (b) amends the definition of authorised representative	Secretary of State
2.14.	This is requirement on the European Commission to produce a report on the workings of the databank to council and the European Parliament.	No requirement to transpose this element into implementing legislation	
2.15.	This brings the health monitoring process in line with the new comitology procedure..	No requirement to transpose this element into implementing legislation	
2.16.	This amends the Article on clinical investigation to introduce the idea of their being a clinical investigation plan and to bring any changes to the clinical investigations provisions in line with the	This is covered in the relevant Annex so has not been transposed.	

	new comitology procedure		
2.17.	This introduces the revised comitology process for changes to the designation criteria for Notified Bodies. Also introduces new elements of information exchanged by Notified Bodies on certificates issued.	No requirement to transpose this element into implementing legislation	
2.18.	Introduces new offence of a "missing" CE mark.	This is already covered under regulation 61 of the principal regulations	Secretary of State
2.19.	Minor amendment with regards to authorised representatives established in the Community.	Regulation2 (b) amends the definition of "authorised representative" in regulation 2 of the Principal Regulations.	Secretary of State
2.20.	In support of transparency in Community legislation, certain information related to medical devices and their conformity with Directive 93/42/EEC, in particular information on registration, on vigilance reports and on certificates, should be available to any	Not being transposed already covered by Part 9 of the Enterprise Act	Secretary of State

	interested party and the public. Also states that decisions on other information which could be made available subject to new comitology procedure		
2.21.	To better coordinate the application and efficiency of national resources when applied to issues related to Directive 90/385/EEC, the Member States should cooperate with each other and at international level	This is a requirement on Member States and is not subject to transposition.	
2.22.	This allows amendments to be made to Annex I-X of Directive 93/42/EEC in line with Annex II of Amending Directive. This Article also references the publication date of national transposition legislation and the coming into force date of the Directive.	The Annexes to Directive 93/42/EC as amended by 2007/47/EC are transposed by cross reference in the Principal Regulation. Regulation 1 details the coming into force date of the amending Regulation.	Secretary of State