

## **Guidance to Changes to the Medical Devices Directive 93/42/EC with respect to custom-made devices statements**

### **Legislative Framework**

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 is 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. The aim is to continue to ensure the highest level of safety, to enable access to the market and to allow the legal framework to function smoothly. Following lengthy negotiation with member states, during which MHRA representing the UK consulted trade and other stakeholder representative organisations, the changes now contained in the Amendment Directive 2007/47/EC were agreed.

### **The Legislative Changes For Custom Made Devices**

#### **Post Market Surveillance**

Two of the changes agreed affect custom-made devices. Firstly 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- Guidance on vigilance generally is available on the MHRA website <http://www.mhra.gov.uk/Howweregulate/Devices/Vigilance/index.htm>.

However most custom made device manufacturers already have a complaints handling system which to comply with the new duty ,they will now need to extend to cover reporting to MHRA . Specifically ,manufacturers will now need to report on any accidents resulting from the constituents or design of the device that pose a potential serious risk to public health , cause in serious incident where they initiate a recall Ordinary return of devices to manufacturers for adjustment or fitting would not need to be reported.

#### **Custom Made Device Statements**

Secondly through an amendment to Article 2.3 of 2007/47/EC a requirement is introduced that the 'Statement' detailed in Article 11.6 and Annex VIII of 93/42/EC should be available to the named patient for whom the device has been manufactured. Previously responsibility rested purely with the custom-made device manufacturer to provide a copy of the statement to the prescriber of the device. The amendment extends this duty by requiring that the statement is available to the patient. Whilst the technical document issued with device should indicate if the manufacturer operates from more than one site, this need not be included in the statement.

The Regulations implementing Directive 2007/47/EC into UK law, which come into force on the 21<sup>st</sup> March 2010, simply requires that patients are made aware that they can request a statement and that it should be made available on request. It does not go into detail about how this will be achieved. This was left to member states to determine as a matter of implementation policy according to national systems for making custom-made devices available to patients.

During the negotiations period MHRA invited all stakeholder representatives affected by the changes to attend discussions on the changes. This was then followed up by visits to manufacturers across the custom made field during the consultation period to explore any practical problems which might arise. .

MHRA then held discussions with representative from the different fields of custom made devices to gain an appreciation of the different ways each of these sectors of the industry would be able to implement the changes. The points made are included in this guidance note as below.

Annex A of this document contains a copy of Annex VIII of the directive which sets out what needs to be included in the manufacturer's statement.

### **Maxillofacial**

The patients for these types of devices are predominantly seen within a clinical environment. The easiest and simplest way of communicating to the patients that the statement is available to them if they wish to have it would be to place posters within the clinics themselves. As these patients records stay with them throughout their treatment the statement itself could be placed on the patient's medical files and would be available to them if requested. The industry journal could be used to alert the health professionals of their responsibility in this area.

Annex B is a sample of a statement provided by Addenbrookes Maxillofacial Unit which could be used by a maxillofacial manufacturer which contains all of the elements needed as in Annex A.

### **Artificial Eyes.**

The National Artificial Eye Service (NAES) operates clinics around the country where patients are seen by their clinicians and the device is then fitted at the clinic when it has been made By the Production Laboratory in Blackpool. The patient's records stay with NAES throughout their treatment period and the statement could be placed on the medical file and accessed when the patient requests to see it. A poster campaign would also work within this environment and could be placed in clinics across the country.

Annex C is a sample of a statement by the eye service which contains all of the elements needed as in Annex A.

### **Dental Devices**

Custom made dental devices are made by dental laboratories by prescription from dentists. The statement in this instance is dispatched by the laboratory (manufacturer) to the dentist with the device. Unlike the previous examples the patients dental records do not provide a history of treatment and prescriptions because they do not move with the patient when he/she changes dentist. Nevertheless the dentist who prescribes and fits the appliance will be the 'health professional' responsible for making the patient aware of the availability of the statement and supplying it on request. To make dentists aware of this obligation, relevant dental journals could carry news items on this requirement change and a press statement from the relevant professional bodies (GDC & BDA) would also ensure the dental profession were aware of their new obligation.

There are a number of ways to consider when informing their patients about the statement and how to obtain it. These range from verbal (at the end of the treatment), posters in the surgery, or a note on the receipt for the treatment charge. If the statement is requested then a signature from the patient to place on their record could be requested by the dentist as proof of fulfilling their obligation. A reference may also be made in the leaflet the Department issues on dental charges.

An example of a statement for custom made dental products provided by the DLA is attached at Annex D which contains all of the elements as at Annex A.

### **External Prosthetics, Orthotics and Wheelchairs including their seating systems.**

In the case of the above custom made devices the statement remains with the healthcare professional. A wheelchair can be a one off custom made device but in the majority of cases a seating system manufactured to the profile/needs of the individual user (custom made device) is fitted to a wheelchair (a medical device) and as is with external prosthetics and orthotics each patient receives a product care leaflet. There could be additional information added to the leaflet informing the patient about the statement, that they can request it and where they can request it from. If it is requested some kind of simple system could be used to confirm receipt by the patient such as a stamp or a signature. The Patients Association could inform their members of the right for them to ask for the statement and possibly a poster campaign could be used to reach this patient group. An example of a statement has been provided by BHTA is attached at Annex E and contains all of the elements as at Annex A.

## ANNEX A

### STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative must draw up the statement containing the information stipulated in Section 2.
2. The statement must contain the following information:
  - 2.1. for custom-made devices:
    - the name and address of the manufacturer,
    - data allowing identification of the device in question
    - a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,
    - the name of the medical practitioner or the authorized person who made out the prescription and, where applicable, the name of the clinic concerned,
    - the specific characteristics of the product as indicated by the prescription,
    - a statement that the device in question conforms to the essential requirements set out in Annex I and ,where applicable ,indicating which essential requirements have not been fully met ,together with the grounds;



ANNEX B

Custom Made Medical Device Document.

Operator : Forename: Peter Surname: Nowak
Address : Maxillofacial Laboratory (Box 47)
Addenbrooke's Hospital NHS Trust
Hills Road
Cambridge
Cambs CB2 2QQ

Maxillofacial Laboratory (Box 47),
AddenBrooke's Hospital N.H.S.Trust,
Hills Road,
Cambridge CB2 2QQ

Tel 01223 216636
Fax 01223 216708
M.D.A. Reg. No. CA002628

Patients Forename: Tester Patients Surname: Specimen
Date: 30/04/2009

Your Ref: 0123456
Our Ref : 006245

Reviewed and accepted subject to sight of positive model.
Date: 30/04/2009 Signed:

Reasons not signed if construction is to proceed:

Device(s): Obturator clear baseplate U/-.

Prescription:
See operators instruction request sheet.

Table with 5 columns: Material, Supplier, Use by Date, Batch No., CE Mark. Contains 3 rows of material data.

b. Reasons not fully met:

Signed: Date dispatched: 01/05/2009

ESSENTIAL REQUIREMENTS
Maxillofacial Laboratory (Box 47), AddenBrooke's Hospital N.H.S.Trust,
Hills Road, Cambridge CB2 2QQ
M.D.A. Reg. No. CA002628
This appliance/Prosthesis:-
a. Is a CUSTOM MADE DEVICE.
b. Has been Manufactured to satisfy the attributes, characteristics, properties and features specified on the prescription. Any relevant essential requirements not met are listed on the Custom Made Medical Device Sheet.
c. Is for exclusive use by the named patient: Tester Specimen
d. Conforms to the essential requirements set out in annex 1 of the Medical Devices Directive 93/42 EEC.
THIS DEVICE IS SUPPLIED IN A NON STERILE STATE.

This statement of conformity has been offered to named patient.
[ ] Accepted [ ] Declined
Signed: \_\_\_\_\_
Guardian: \_\_\_\_\_
Date: \_\_\_\_\_



**ANNEX C**



***The National  
Artificial Eye Service***

**Custom Made Medical Device**

Manufactured by: -

The National Artificial Eye Service  
221 Bristol Avenue  
Blackpool  
Lancashire FY2 0BF

The artificial eye is intended for the exclusive use of .....

Order number.....

Orbital Prosthetist.....

Clinic.....

This custom made artificial eye has been manufactured to the specification provided by the above named Orbital Prosthetist

The device conforms to the essential requirements of Annex 1 of Medical Device Directive 93/42/EEC

Signed.....Print name.....

Date.....

This Statement of conformity has been offered to the named patient.

- Accepted                       Declined

Signed.....

Guardian.....

Date.....

**ANNEX D**

**EXAMPLE B - PATIENT PRESCRIPTION & INFORMATION**

<p><b>A N Other Dental Laboratory</b>                  44 Wollaton Road                  Nottingham NG9 2NR                  0115 9254888</p>  <p>REGISTERED WITH THE UK COMPETENT AUTHORITY CA00000</p>		<p><b>PATIENT PRESCRIPTION AND CUSTOM MADE APPLIANCE INFORMATION</b></p> <p><i>If you have any queries regarding the fit or performance of your appliance you should contact the prescribing dentist for further information.</i></p>		
<b>PATIENT'S NAME</b>		<b>NAME OF PRESCRIBER</b>		<b>CLINIC NAME AND ADDRESS</b>
<b>DATE OF APPLIANCE MANUFACTURE</b>		<b>ISSUE DATE OF TECHNICAL REPORT</b>		<b>LAB REFERENCE</b>
<i>Product Code</i>	<i>Description/Type of Appliance</i>	<i>Quantity</i>	<i>Standard of work NHS/Private</i>	<i>Comments</i>
<b>ORIGIN OF MANUFACTURE DECLARATION</b>				
<p>This complete appliance has been wholly manufactured within the EU.</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p> <p>(If no, detail manufacturing locations below)</p> <p>1. _____</p> <p>2. _____</p>				
<p><b>Your attention is drawn to the following statement:</b> This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.</p> <p><i>This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient's use.</i></p>				

**EXAMPLE A – COMBINED LABORATORY TICKET  
& PATIENT PRESCRIPTION/INFORMATION**



<p align="center"><b>A N Other Dental Laboratory</b> 44 Wollaton Road Nottingham NG9 2NR 0115 9254888</p> <p align="center"><small>REGISTERED WITH THE UK COMPETENT AUTHORITY CA00000</small></p>	<p align="center"><b>TWO-PART CUSTOM-MADE DENTAL APPLIANCE PRESCRIPTION</b></p> <p align="center"><i>Please complete the appropriate sections of this prescription and send both parts to the address opposite. If you have any problems with the use of this prescription then phone us on 0115 9254888.</i></p>
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<b>PATIENT'S NAME</b>	<b>NAME OF PRESCRIBER</b>	<b>CLINIC NAME AND ADDRESS <i>(if applicable)</i></b>
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<b>Date sent:</b>	<b>Date required</b>	<b>Lab reference <i>(where applicable)</i></b>
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<b>Type of appliance</b>	Orthodontic	Denture	Metal casting	Crown & Bridge	Bite raiser	Splint
	Obturator	Facial prosthesis	Body prosthesis	Nightguard	Implant	Bleaching tray
<b>Please [Y]</b>						

**INSTRUCTIONS AND AMENDMENTS RECORD**

**OUTLINE OF DESIGN REQUIRED**

***FIELDS BELOW TO BE COMPLETED BY LABORATORY PERSONNEL ONLY***

<b>Approved for manufacture by:</b>  <i>Sign:</i>	<b>Approved for release by:</b>  <i>Sign:</i>
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<b>Details of materials etc supplied by prescriber</b>  <b>Initials:</b>	<b>Details of any model approval by prescriber</b>  <b>Initials:</b>
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***ORIGIN OF MANUFACTURE DECLARATION***

This complete appliance has been wholly manufactured within the EU.

Yes  
 No

**(If no, detail manufacturing locations below)**

3. \_\_\_\_\_

4. \_\_\_\_\_

***Your attention is drawn to the following statement:*** This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.

*This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient's use.*

***Storing, handling and instructions for use:*** It is recommended that before use, this medical device is stored in a clean and safe environment that prevents it from coming into contact with materials, equipment, acids, alkalies or bleaches that could cause physical or chemical damage to the medical device. The medical device should not be subjected to extremes of temperature during storage. Where applicable, you should take care not to damage the medical device when removing it from its model. Where applicable, instructions on how to use or clean this medical device may be obtained from the prescriber.



**ANNEX E**

**DRAFT**

**MANUFACTURER'S  
LETTERHEAD**

**CUSTOM MADE MEDICAL DEVICE**

This custom made orthotic is intended  
for the exclusive use of .....  
Patient's Name

Order number:.....

Orthotist/Prosthetist:.....

Clinic:.....

This custom made orthotic has been manufactured for the above patient to the  
specification provided by the above named clinician.

The device conforms to the essential requirements of Annex 1 of Medical Device Directive  
93/42/EEC

Signed.....

Print name.....

Date.....

*NB: The patient can obtain a copy of this statement by contacting the  
manufacturer of the device and quoting the order number above.*