Examples of statements for custom-made medical devices

The following products are listed for guidance only. Some of these products will also be available as mass-produced, rather than custom-made medical devices and must be classified according to Part II of the UK Medical Devices Regulations 2002 (as amended) (UK MDR 2002), Annex IX as modified by Part I of Schedule 2A to the UK MDR 2002).

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. Below is a sample of a statement provided by Addenbrookes Maxillofacial Unit, containing all of the elements needed in the statement, which could be used by a maxillofacial manufacturer.

Custom Made Medical Device Document.

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

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

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 UI-.

Prescription:
See operators instruction request sheet.

Material	Supplier	Use by Date	Batch No.	CE Mark
Stainless steel wire 0.9mm dia	K.C.Smith, Moemouthshire		099021	Yes
Acrylic H/C C&J Delux powder (veined)	Chaperlin & Jacobs	31/03/2010	Lot 05CP01	Yes
Acrylic Universal Denture liquid clear	Bracon Ltd	30/09/2010	Lot 20136	Yes

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:

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. Below is a sample of a statement by the eye service which contains all of the elements needed in the statement.

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 (Part II of the UK MDR 2002, Annex I [as modified by Part II of Schedule 2A to the UK MDR 2002])

Signed……Print name…….
Date……
This statement of conformity has been offered to the named patient.
□ Accepted □ Declined
Signed……..
Guardian……...
Date…….

Dental devices

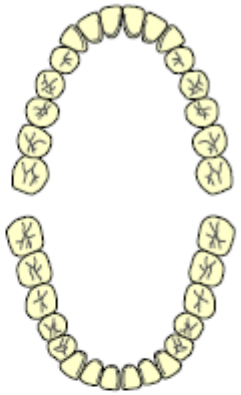
Custom-made dental devices are made by dental laboratories by prescription from dentists. The statement in this instance is dispatched by the laboratory (manufacturer) to the dentist with the device. Unlike the previous examples the patient's dental records do not provide a history of treatment and prescriptions 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 dental professionals were aware of their obligation.

There are a number of ways to inform patients about the statement and how they can 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 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 below which contains all of the elements in the statement.

Example A – combined laboratory ticket and patient prescription/information

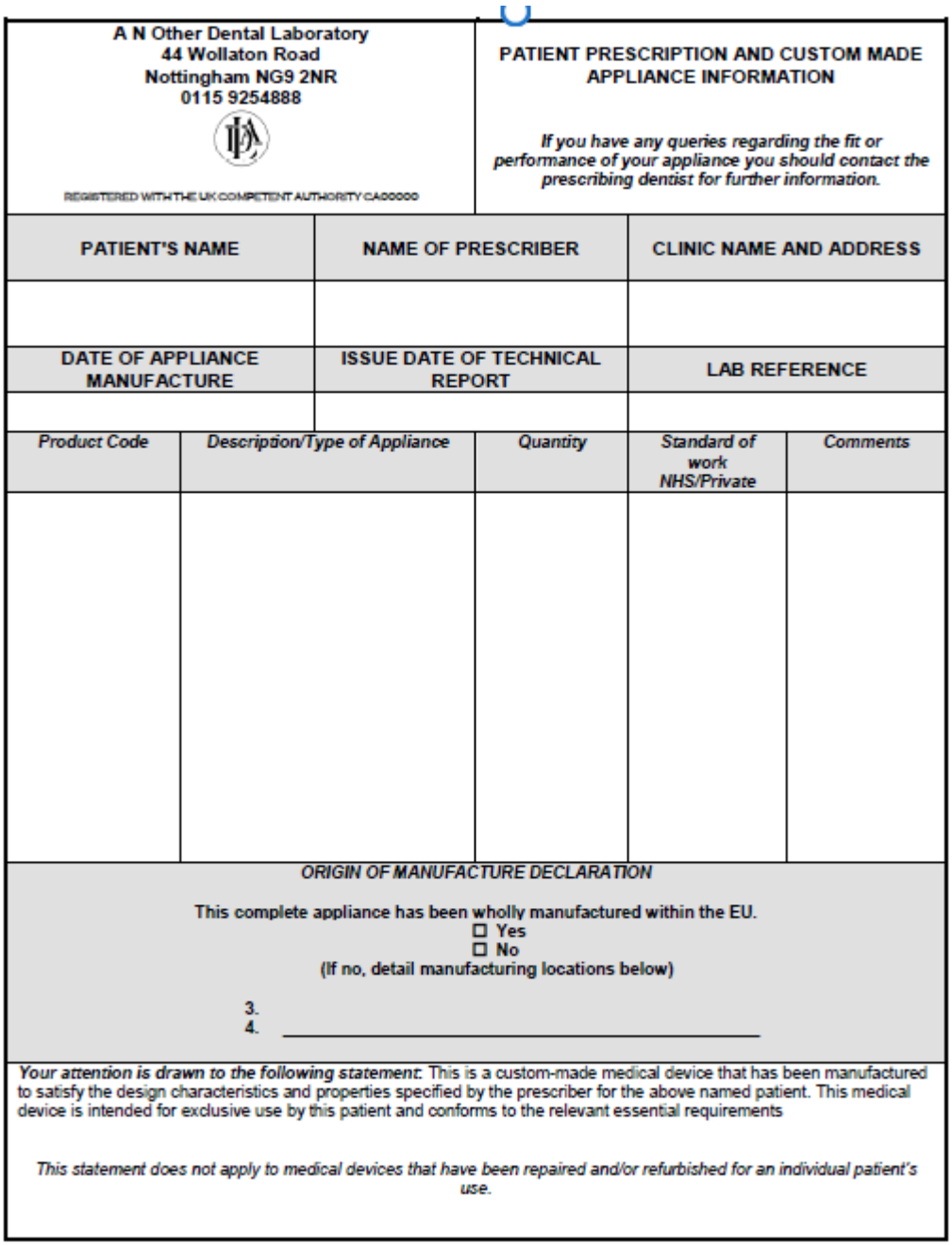
A N Other Dental Laboratory **44 Wollaton Road** **Nottingham NG9 2NR** **0115 9254888**				**TWO-PART CUSTOM-MADE DENTAL APPLIANCE PRESCRIPTION** ***Please complete the appropriate sections of this prescription and send both parts to the address opposite. If you have any problems with the use of this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

INSTRUCTIONS AND AMENDMENTS RECORD	OUTLINE OF DESIGN REQUIRED
	
FIELDS BELOW TO BE COMPLETED BY LABORATORY PERSONNEL ONLY	
Approved for manufacture by: ***Sign:***	**Approved for release by:** ***Sign:***
Details of materials etc supplied by prescriber **Initials:**	**Details of any model approval by prescriber** **Initials:**
ORIGIN OF MANUFACTURE DECLARATION **This complete appliance has been wholly manufactured within the EU.** ☐ **Yes** ☐ **No** **(If no, detail manufacturing locations below)** 1. _____ 2. _____	
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 *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.	

For the purposes of the above diagram, please read:

- ‘EU’ as ‘UK’

Example B - patient prescription and information



A N Other Dental Laboratory
44 Wollaton Road
Nottingham NG9 2NR
0115 9254888

REGISTERED WITH THE UK COMPETENT AUTHORITY CA00000

PATIENT PRESCRIPTION AND CUSTOM MADE APPLIANCE INFORMATION

If you have any queries regarding the fit or performance of your appliance you should contact the prescribing dentist for further information.

PATIENT'S NAME	NAME OF PRESCRIBER	CLINIC NAME AND ADDRESS
DATE OF APPLIANCE MANUFACTURE	**ISSUE DATE OF TECHNICAL REPORT**	**LAB REFERENCE**

Product Code	*Description/Type of Appliance*	*Quantity*	*Standard of work NHS/Private*	*Comments*

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

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

For the purposes of the above diagram, please read:

- 'EU' as 'UK'

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, and how they can request it. If it is requested, a 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 the British Healthcare Trade Association is attached below and contains all elements in the statement.

DRAFT

Manufacturers name and address:

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 (Part II of the UK MDR 2002, Annex I [as modified by Part II of Schedule 2A to the UK MDR 2002]).

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.