**UK manufactured Custom-Made Dental Devices as regulated by the MHRA**.[[1]](#endnote-1)

**This Statement is provided for the patient.**[[2]](#endnote-2)

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| --- | --- | --- |
| **Manufacturer:**  (Your Address)  MHRA registration number: **CAxxxxx** | **Patient / User:**  Patient code: e.g. AD-Patient 00630-M | **Prescribing clinician:**  Mrs/Ms/Mr XXXXXX  GDC registration No. XXXXXX  ...and if applicable the Health Institution or Hospital.  (NB: adding the delivery address could be useful) |

For your information:

**1.0** This custom-made dental device being the manufacturer’s reference **No: ..........** is intended for the exclusive use by you the patient/user as identified above.

**2.0 The specific details of the custom-made dental device/s as prescribed by the clinician is summarised below** (*as taken from the prescription*)

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|  |

**3.0 Other details or comments related to this / these device/s if necessary**

|  |  |
| --- | --- |
| i) Specific detailed requests added, if any. |  |
| ii) Modification agreed with the prescriber, if any. |  |
| iii) If required, an indication of which general safety and performance requirements have **not** been fully met, together with the grounds. |  |

**4.0** Manufacturer’s **statement:** This appliance has been manufactured in the UK in conformity with the Medical Devices Regulations [MDR] (Regulation 2017/745 EU) meeting the general safety and performance requirements. It has been manufactured to the prescription of an appropriate clinician and by using materials that are specifically for the purpose of this/ these appliances, and which have been authorised to be used in such situations to meet the requirements of Annex 1 of the MDR regulations. Where modifications to the original prescription have been made, these will have been agreed with the prescriber and are documented in 3.0 above. This /these dental appliance/s, have been manufactured in the UK and are signed off as meeting the design characteristics and requirements stated or implied by the above-named prescriber. This signature below is our declaration of conformity.

Signature: Date placed on the market:

Name in block capitals: GDC registration number:

**5.0 General safety and guidance to the patient**

As a patient/user your attention is drawn to the information and guidance provided by the attending clinician, and the need to maintain personal oral hygiene using the guidance provided and the appropriate dental cleaning products. You should not use general cleaning products on removable custom-made dental devices as such can adversely affect the colour, surface structure and other physical properties.

**6.0 The patients/ users support in the ongoing quality assurance process**

Any concerns or issues that you as a patient/user experience with the appliance/s should always be referred directly back to the prescribing dentist/clinician. This then also assists in providing what is termed ‘post market surveillance’ of these custom-made devices. Thank you for your cooperation.

1. Medicine and Healthcare Regulatory Authority (MHRA) – an overview of custom made devices directive 2007/47/E.

   <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/398428/Custom_made_devices.pdf> [↑](#endnote-ref-1)
2. MDR regulations, in the Article 21 (2) <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN> [↑](#endnote-ref-2)