

**APPLICATION FOR THE USE OF A NON - C E MARKED DEVICE ON  
HUMANITARIAN GROUNDS  
(For completion by the consultant)**

**Name and address of consultant (please include telephone, fax and email details):**

**Name of Manufacturer:**

**Device to be used:**

**Name of Patient:**

**Date of Birth:**

**Details of patient's medical condition:**

**Reason for device's necessity:**

**Consequence to patient's condition if device is not used:**

**Further information:**

**Declaration:** It is my opinion that the patient's condition will deteriorate without the use of the above - named device and that there is no other device available on the market that will fulfil the function required. The patient has been informed of, and has explicitly consented to his/her name, date of birth and medical details being provided to the MHRA in this application for the purpose of allowing the MHRA to assess the application under 26(3) of the Medical Devices Regulations 2002, Part III – Active Implantable Medical Devices.

**Signed:** ..... **Date:** .....

**Name (printed)**.....

**APPLICATION FOR THE USE OF A NON - C E MARKED DEVICE ON  
HUMANITARIAN GROUNDS**  
(For completion by manufacturer)

**Name and address of supplier:**

**Name and address of Manufacturer:**

**Generic name of device:**

**Number of identical/similar devices currently in use:**

**Details of any clinical investigations currently using device and names of responsible or controlling authorities:**

**Details of aspects of device that differentiate it from other devices already on the market:**

**Further information including a risk analysis, identification of hazards, estimation of risks and how such risks have been addressed, together with information to support a positive risk benefit analysis :**

**Signed: .....** **Date: .....**

**Name (printed).....**

