

CERTIFICATE OF FREE SALE CHECKLIST

What needs to be submitted to the HPRA	Completed
1. a) Complete the relevant application form and send by email to devices@hpra.ie . or b) If requesting a certificate of free sale that has already been issued, provide the HPRA with the certificate number.	<input type="checkbox"/> <input type="checkbox"/>
2. Proof of payment (e.g. cheque, bank draft/transfer credit on account) (see 'Guide to Fees' and the 'Fee Application Form' for more details).	<input type="checkbox"/>
3. For CE marked products: a) A copy of the notified body certificates for all CE marked products. or b) The HPRA of the device registration number for MDD and IVDD devices registered with the HPRA.	<input type="checkbox"/> <input type="checkbox"/>
4. Ensure that the accompanying Excel or Word file for device details is ≤30 pages.	<input type="checkbox"/>
5. Declaration of conformity or proof of manufacture listing the devices concerned by item/product code and description, along with the physical site of manufacture.	<input type="checkbox"/>
6. Ensure all documents are in English, or in Irish and English.	<input type="checkbox"/>