務の責任者その他これらに相当する者について記載すること。

In the section 2, write the name and address of a person who has the right to decide to ship or not to ship products, or the manufacturing control manager or quality control manager or a person in a position equivalent to the foreign mentioned positions.

２　記の３については、該当しない場合は「該当しない」と記載し、該当する場合には、該当する事案の概要を記載すること。

In the section 3, write not applicable if the applicant does not correspond, and write a summary of the relevant details if the applicant does correspond.

３　申請者が他の医療機器等外国製造業者の登録を受けている場合には、記の４に当該登録の登録番号を、医薬品等外国製造業者又は再生医療等製品外国製造業者の認定を受けている場合には、記の４に当該認定の区分及び認定番号を記載すること。

If the applicant has been registered as a foreign animal medical device or in vitro diagnostic manufacturer, write the number of registration in the section 4, if the applicant has been accredited as a foreign animal drug or quasi-drug manufacturer in a different accreditation category, or as a foreign regenerative, cellular therapy and gene therapy products manufacturer, write that category and the number of accreditation in the section 4.

４　申請書は、正副２通を提出すること。

Applicant should submit one original and one copy of it.