Appendix A

Application for performance of a conformity assessment procedure in accordance with 90/385/EEC (AIMD)

Manufacturer: _____ **Application identification:** _____

Product Service

Appendix A

Device details

☐ AIMD 0101 Active implantable medical devices for stimulation / inhibition

☐ AIMD 0102 Active implantable medical devices delivering drugs or other substancess

☐ AIMD 0103 Active implantable medical devices substituting or replacing organ functions

	Name of model Trade name	Model (number(s)) *1)	Name (from UMDNS)	UMDNS Code *2)	OEM Device	manufactured utilizing animal tissues or derivatives rendered non-viable	Incorporates a substance which if used separately may be considered to be a medicinal product as defined in Directive 2001/83/EC or a human blood derivative
1.					☐	☐	☐
2.					☐	☐	☐
3.					☐	☐	☐
4.					☐	☐	☐
5.					☐	☐	☐
6.					☐	☐	☐
7.					☐	☐	☐
8.					☐	☐	☐
9.					☐	☐	☐

*1) This information is only required for product-related procedures (i.e. only for procedures in accordance with Annex 2.4, 3, 4).
*2) The **UMDNS Code** is only required for product-related procedures for reporting to DIMDI.