



Product Service

# Appendix A ?

Details on product groups and categories (conformity assessment procedure in accordance with Directive 93/42/EEC (MDD))

? **Manufacturer:**

? **Application identification:**

## Device details per certificate number ?

This form may be used as a list if filled accurately. You can also use it as a template and provide **the same information** in other formats (e.g. Excel).

**Certificate number:**

<span>?</span> Category*	All article/model numbers	Article/Model names	<span>?</span> Class	<span>?</span> Sterile	<span>?</span> Rule	UMDNS code	<span>?</span> OEM device	OEM name Please enclose the relevant certificates of the OEM (Original Equipment Manufacturer).	<span>?</span> Annex IX, Rule 17	<span>?</span> Annex IX, Rule 13
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

\* Please quote here:

- Consistent with proposed certification scope.
- For all classes of Medical Devices: the respective scope expression on the basis of [NBOG BPG 2009-3](#) including the special MDS codes e.g nano materials.
- Additionally for class IIb/III Medical Devices: the respective preferred terms from the [GMDN](#).
- Only in cases where the scope expression or preferred terms are not existing: indicate your own category.